United States Government Accountability Office

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Report to the Chairman, Committee on Environment and Public Works, U.S. Senate

March 2008

CHEMICAL ASSESSMENTS

Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System

GAO-08-440

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Highlights

Highlights of GAO-08-440, a report to the Chairman, Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) contains EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals. IRIS is a critical component of EPA's capacity to support scientifically sound environmental decisions, policies, and regulations. GAO was asked to examine (1) the outcome of steps EPA has taken to ensure that IRIS contains current, credible chemical risk information, to address the backlog of ongoing assessments, and to respond to new requirements from the Office of Management and Budget (OMB); and (2) the potential effects of planned changes to the IRIS assessment process on EPA's ability to ensure that IRIS provides current, credible risk information. To do this work, GAO reviewed and analyzed EPA data and interviewed officials at relevant agencies.

What GAO Recommends

GAO recommends that EPA (1) clearly define and document an IRIS assessment process that, among other things, can be conducted within a time frame that minimizes the need for rework and (2) ensure that it can develop transparent, credible assessments by, for example, determining the types of IRIS assessments it will conduct based on EPA program needs and defining the appropriate role of other federal agencies in its IRIS assessment process. EPA agreed to consider GAO's recommendations in revising the IRIS assessment process.

To view the full product, including the scope and methodology, click on GAO-08-440. For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

What GAO Found

EPA's actions since 2000 to ensure that IRIS contains current, credible risk information, to address its backlog of 70 ongoing assessments, and to respond to new OMB requirements—including increasing funding and revising the assessment process—have not enabled EPA to routinely complete credible IRIS assessments or decrease its backlog. Although in fiscal years 2006 and 2007 EPA sent 32 assessments to OMB for the first of three required external reviews, EPA finalized only 4 assessments during this period. This low level of productivity jeopardizes the viability of the IRIS database. Further, an EPA analysis indicated that many existing assessments may need to be updated, and EPA program offices and other IRIS users have requested assessments of hundreds of chemicals not yet in IRIS. Factors contributing to EPA's inability to complete IRIS assessments in a timely manner include new OMB-required reviews of IRIS assessments by OMB and other federal agencies; certain EPA management decisions, such as delaying some assessments to await new research; and the compounding effect of delays—even one delay can have a domino effect, requiring the process to essentially be repeated to incorporate changing science. As of December 2007, most of the 70 ongoing assessments had been in progress for over 5 years.

Regarding new OMB requirements, the IRIS assessment process now includes two OMB/interagency reviews of draft assessments. These reviews have resulted in involvement of other federal agencies in EPA's IRIS assessment process in a manner that limits the credibility of IRIS assessments and hinders EPA's ability to manage them. That is, the OMB/interagency reviews lack transparency—OMB considers agencies' comments on IRIS assessments to be internal executive branch documents that may not be made public. Given the importance of IRIS assessments, it is essential that input from all parties, including other federal agencies, be part of the public record. Transparency is especially important because agencies providing input include those that may be affected by the assessments should they lead to regulatory or other actions. Also, without communicating its rationale for doing so, OMB directed EPA to terminate five assessments that for the first time addressed acute, rather than chronic, exposure—even though EPA initiated this type of assessment to help it implement the Clean Air Act. Most OMB/interagency reviews completed to date have added 6 or more months to the IRIS time frames.

Such delays and credibility concerns would likely be exacerbated by further changes EPA is planning to respond to continuing concerns of other federal agencies, such as providing them with an expanded role in EPA's IRIS assessment process and discretion to suspend assessments to develop new studies for some chemicals. EPA estimates that such assessments would take up to 6 years, an estimate GAO believes is conservative in light of the assessment time frames under the current process. Suspending assessments is inefficient; alternatively, with longer-term planning, EPA could provide agencies and the public with more advance notice of assessments, enabling them to complete relevant research before IRIS assessments are started.

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Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
DOD	Department of Defense
DOE	Department of Energy
EPA	Environmental Protection Agency
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
NASA	National Aeronautics and Space Administration
NCEA	National Center for Environmental Assessment
NCI	National Cancer Institute
NIOSH	National Institute of Occupational Safety and Health
OMB	Office of Management and Budget
ORD	Office of Research and Development
PART	Program Assessment Rating Tool
PBPK	physiologically based pharmacokinetic
RfC	inhalation reference concentration
RfD	oral reference dose
TCE	trichloroethylene

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Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

March 7, 2008

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate

Dear Madam Chairman:

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS)—a database integral to the agency's mission of protecting human health and the environment—contains EPA's scientific position on the potential human health effects that may result from exposure to various chemicals in the environment. IRIS data provide the fundamental scientific components needed to develop human health risk assessments. These health risk assessments, in turn, provide the foundation for risk management decisions, such as whether EPA should establish air and water quality standards to protect the public from exposure to toxic chemicals or set cleanup standards for hazardous waste sites. In addition, state and local environmental programs, as well as some international regulatory bodies, rely on IRIS health effects information in managing their environmental protection programs. Although the information in IRIS is a critical primary component of EPA's capacity to support scientifically sound decisions, policies, and regulations, many IRIS assessments are outdated, and few assessments have been completed in recent years. This has resulted in a significant backlog of incomplete chemical assessments and a growing number of outdated assessments. Further, while EPA's IRIS database currently includes about 540 chemicals, every year approximately 700 new chemicals enter commerce, any number of which could pose significant human health risks.

Overall, the goal of the IRIS assessment process is to produce quantitative estimates of cancer and noncancer effects from chronic (long term) exposure to the chemicals assessed. One impact of not having current and complete IRIS assessments of many potentially harmful chemicals is that some chemicals that pose health risks to the public may not be regulated under, for example, air or drinking water statutes, or are regulated by standards that may not sufficiently take into account the best available science on human health effects. For example, trichloroethylene (TCE), a solvent widely used as a degreasing agent in industrial and manufacturing settings, is the most frequently reported organic contaminant in

groundwater and has been linked to cancer and other health hazards, according to the National Academies.[1] Yet, because of questions raised by peer reviewers about the IRIS cancer assessment for TCE, EPA withdrew the assessment from IRIS in 1989, did not initiate a new TCE assessment until 1998, and likely will not complete that assessment until 2010 or later. This delay represents an information gap of at least 21 years. Without completed IRIS assessments reflecting current risk data, EPA lacks assurance that its regulatory decisions concerning this widespread chemical reflect the best available science on its potential health effects.

While the IRIS assessment process includes numerous individual steps or activities, major assessment steps include (1) a review of the scientific literature; (2) preparation of a draft IRIS assessment; (3) internal EPA reviews of draft assessments; (4) two Office of Management and Budget (OMB)/interagency reviews, managed by OMB that provide for input from OMB as well as from other federal agencies, including those that may be affected by the IRIS assessments if they lead to regulatory or other actions; (5) an independent peer review conducted by a panel of experts; and (6) the completion of a final assessment that is posted to the IRIS Web site. EPA's assessment process has undergone a number of formal and informal changes during the past several years. The agency is planning further changes—particularly in the areas of external reviews and scientific data gaps—largely to address concerns of other federal agencies, such as the Department of Defense (DOD). Some of the assessment process changes have raised concerns about EPA's ability to keep its scientific assessments separate from its risk management decisions, as the National Academies recommends and EPA policy endorses.

In this context, this report examines (1) the outcome of steps EPA has taken to ensure that IRIS contains current, credible chemical risk information, to address the backlog of IRIS assessments, and to respond to new requirements from OMB; and (2) the potential effects of EPA's planned changes to the IRIS assessment process on EPA's ability to ensure that IRIS provides current, credible risk information.

In conducting our work, we obtained and analyzed information on EPA's productivity, including the number of new and completed IRIS

[1]The National Academies comprises four organizations: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council.

assessments, for fiscal years 2000 through 2007; the status of IRIS assessments, as of December 1, 2007, that were in progress during fiscal year 2007; the status of IRIS assessments that have been sent to OMB for OMB/interagency review; the number of assessments in the IRIS database that may need to be updated; the resources provided to the program for fiscal years 2000 through 2007; and user needs and EPA's assessment completion goals. We interviewed EPA's National Center for Environmental Assessment officials who manage the IRIS assessment program, as well as officials from other EPA program offices and federal science and health agencies that are involved in the IRIS assessment process, to obtain their perspectives on, among other things, the current IRIS assessment process, the potential effects of the proposed changes to the process, the extent to which EPA has made progress in completing assessments and meeting user needs, and challenges EPA faces in completing assessments. In addition, we also interviewed officials from the Department of Defense, the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), and OMB to obtain their perspectives on the OMB/interagency review process and on the planned changes to the IRIS assessment process. We did not evaluate the scientific content or quality of IRIS assessments. (See app. I for a more detailed description of the methodology we employed.) We conducted our work from October 2006 to March 2008 in accordance with generally accepted government auditing standards, which require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

EPA has taken a number of steps to help ensure that IRIS contains current, credible chemical risk information, to address its backlog of ongoing assessments, and to respond to new OMB requirements. However, to date, these changes—including increasing funding, centralizing staff conducting assessments, and revising the assessment process—have not enabled EPA to routinely complete credible IRIS assessments or decrease the backlog. That is, although EPA sent 32 draft assessments for external review in fiscal years 2006 and 2007, the agency finalized only 4 IRIS assessments during this time. Several key factors have contributed to EPA's inability to achieve a level of productivity that is needed to sustain the IRIS program and database: new OMB-required reviews of IRIS assessments by OMB and other federal agencies; the growing complexity and scope of risk assessments; certain EPA management decisions and issues, including delaying completion of some assessments to await new research or to

develop enhanced analyses of uncertainty in the assessments; and the compounding effect of delays. Regarding the last factor, even a single delay in the assessment process can eventually lead to the need to repeat the assessment process to take into account changes in science and methodologies. A variety of delays have impacted the majority of the 70 assessments being conducted as of December 2007—causing them to be in process for more than 5 years. These time frames are problematic because of the substantial rework such cases often require to take into account changing science and methodologies before they can be completed. Further, because EPA staff time continues to be dedicated to completing these assessments, EPA's ability to both keep the more than 540 existing assessments up to date and initiate new assessments is limited. Importantly, EPA program offices and state and local entities have requested assessments of hundreds of chemicals not yet in IRIS, and EPA data as of 2003 indicated that the assessments of 287 chemicals in the database may be outdated—that is, new information could change the risk estimates currently in IRIS or enable EPA to develop additional risk estimates for chemicals in the database. In addition, because EPA's 2003 data are now more than 4 years old, it is likely that more assessments may be outdated now.

One of the factors that has contributed to EPA's inability to complete assessments in a timely manner—the new OMB/interagency review process—also limits the credibility of the assessments because it lacks transparency.[2] Specifically, neither the comments nor the changes EPA makes to the scientific IRIS assessments in response to the comments made by OMB and other federal agencies, including those whose workload and resource levels could be affected by the assessments, are disclosed. According to OMB, the comments it provides to EPA and EPA's disposition of them are considered internal executive branch communications that may not be made public. Further, OMB has not communicated its rationale for directing EPA to discontinue work on five IRIS assessments that EPA had sent to OMB for OMB/interagency review. These assessments, initiated to meet EPA program needs, were the first EPA IRIS assessments of short-term (acute) risks of exposure; the IRIS program historically has evaluated long-term (chronic) risks.

[2]Transparency is relevant to both the IRIS assessment process (for example, the public availability of information about the assessment process, the input from external reviews on draft assessments, and EPA's responses to them) and the content of IRIS assessments (for example, the rationale for using specific data sets, assumptions, or models). In this report, the transparency issues we discuss primarily relate to the IRIS assessment process.

The additional assessment process changes EPA is planning would likely exacerbate delays in completing IRIS assessments and further affect their credibility. Specifically, despite the informal OMB/interagency review process that OMB required EPA to incorporate into the IRIS assessment process in 2005, certain federal agencies continue to believe they should have greater and more formal roles in EPA's development of IRIS assessments. Consequently, EPA has been working for several years to establish a formal IRIS assessment process that would expand the role of federal agencies in the process—including agencies such as DOD, which could be affected by the outcome of IRIS assessments. Some of these agencies and their contractors could face increased cleanup costs and other legal liabilities if EPA issued an IRIS assessment for a chemical that resulted in a decision to regulate the chemical to protect the public. Under EPA's planned changes, these potentially affected agencies would be able, at several points in the assessment process, to subject particular chemicals of interest to additional process steps. EPA estimates that these assessments would take up to 6 years to complete because, for example, at the discretion of these agencies, EPA would suspend the assessment process for up to 18 months so the agencies could conduct additional research to fill data gaps, rather than proceeding with currently available data. While it is important to ensure that assessments consider the best science, EPA has acknowledged that waiting for new data can result in substantial harm to human health, safety, and the environment. Further, although coordination with other federal agencies about IRIS assessments could enhance the quality of the assessments, increasing the role of agencies that may be affected by IRIS assessments in the process itself reduces the credibility of the assessments if that expanded role is not transparent. In this regard, while EPA planned to include federal agencies' comments in the public record, the process changes have been delayed since early 2007 in part because of OMB's view that agencies' comments about IRIS assessments represent internal executive branch communications that may not be made public—a view that is inconsistent with the principle of sound science that relies on, among other things, transparency.

We are making recommendations to the EPA Administrator to require the Office of Research and Development to re-evaluate its draft proposed changes to the IRIS assessment process in light of the issues raised in this report and ensure that any revised process, among other things, clearly defines and documents an IRIS assessment process that will enable the agency to develop the timely chemical risk information it needs to effectively conduct its mission. In addition, we are recommending that the EPA Administrator take steps to better ensure that EPA has the ability to

develop transparent, credible IRIS assessments, including determining the types of assessments it needs to support its programs; defining the appropriate role of external federal agencies in EPA's IRIS assessment process; and managing an interagency review process in a manner that enhances the quality, transparency, timeliness, and credibility of IRIS assessments.

We provided EPA and OMB with a draft of this report for review and comment. EPA agreed to consider our recommendations in revising the IRIS assessment process. However, EPA stated that it believed the productivity and transparency issues discussed in the draft report were misrepresented in the title and body of the report. We disagree and believe we have fairly represented IRIS productivity and transparency issues related to the IRIS assessment process. We did, however, clarify that the transparency issues highlighted in our report focus on the IRIS assessment process rather than on the content of IRIS assessments, and we revised the report title. In its comments, OMB did not specifically address the recommendations we made to EPA but disagreed with some aspects of the report, such as our characterization of the purpose and effect of the OMB-managed interagency reviews of IRIS assessments and our conclusion that interagency comments should be transparent. We disagree with OMB and believe that we have fairly represented the OMB/interagency review process as well as the importance of making input from all parties publicly available to alleviate concerns of potential bias. EPA's and OMB's letters and our detailed responses are discussed further at the end of this report and in appendixes IV and V.

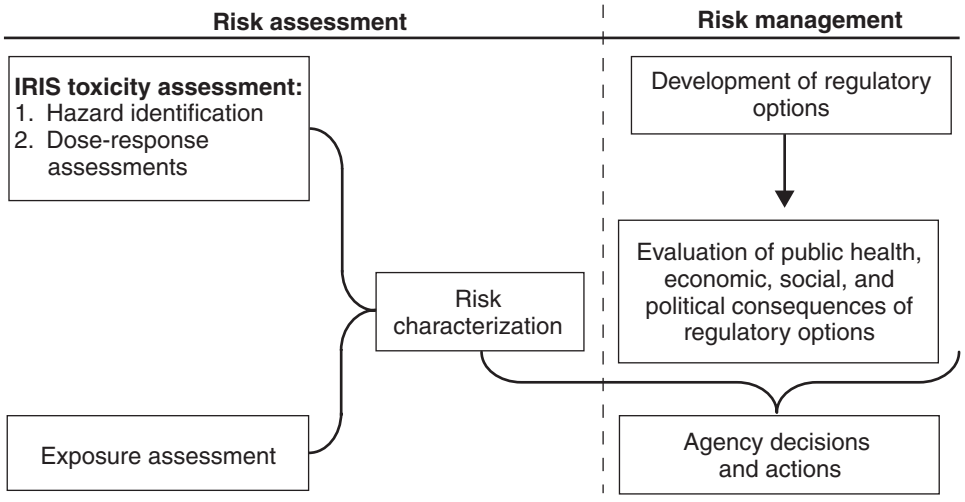
Background

EPA's Integrated Risk Information System (IRIS) is an important source of information on health effects that may result from exposure to chemicals in the environment. IRIS was created in 1985 to help EPA develop consensus opinions within the agency about the health effects from chronic exposure to chemicals, and its importance has increased over time as EPA program offices and the states have increasingly relied on IRIS information in making environmental protection decisions. Today, the IRIS database—which currently contains assessments of more than 540 chemicals—is heavily relied upon by EPA, state and local environmental programs, international regulatory bodies, academia, industry, and others to support risk-based decision making to protect public health and the environment. According to EPA, national and international users access the IRIS database approximately 9 million times a year. EPA's Assistant Administrator for the Office of Research and Development has described IRIS as the premier national and international source for qualitative and

quantitative chemical risk information; other federal agencies have noted that IRIS data is widely accepted by all levels of government across the country for application of public health policy, providing benefits such as uniform, standardized methods for toxicology testing and risk assessment, as well as uniform toxicity values. Similarly, a private-sector risk assessment expert has stated that the IRIS database has become the most important source of regulatory toxicity values for use across EPA's programs and is also widely used across state programs and internationally.

As shown in figure 1, the toxicity assessments in the IRIS database fulfill the first two critical steps of the risk assessment process—providing hazard identification and dose-response assessment. IRIS information can then be used with the results of exposure assessments (typically conducted by EPA's program or regional offices) to provide an overall characterization of the public health risks for a given chemical in a given situation. The risk characterization information can be used to make risk management decisions designed to protect public health. The development of risk assessments is thus directly dependent on the development of toxicity assessments such as those developed in the IRIS program.

Figure 1: National Academies' Risk Assessment and Risk Management Model Used by EPA



Source: National Academies.

Risk management, as opposed to risk assessment, involves integrating the risk characterization information generated from the risk assessment with other information, such as economic information on the costs and benefits

of mitigating the risk, technological information on the feasibility of managing the risk, and the concerns of various stakeholders, to decide how to protect public health. An initial risk management decision would be to determine whether the health risks identified in a chemical risk assessment warrant regulatory or other actions. Examples of subsequent risk management decisions that could stem from a determination that action is necessary to protect public health include deciding (1) how much of a chemical a company may discharge into a river; (2) which substances may be stored at a hazardous waste disposal facility; (3) the extent to which a hazardous waste site must be cleaned up; (4) permit conditions for treatment, storage, or disposal of hazardous waste; (5) levels for air emissions; and (6) allowable levels of contamination in drinking water. Thus, as EPA has recognized, although IRIS assessments are not regulatory in nature, the quantitative IRIS values may influence many environmental decisions and may serve as a basis for regulatory consideration.

A typical IRIS assessment contains a qualitative hazard identification description and quantitative dose-response assessments. Among other things, a hazard identification description identifies the potential noncancer and cancer health effects of exposure to a chemical that research studies have suggested or determined. For example, for cancer effects, EPA describes the potential health risk using one of five weight-of-the-scientific-evidence descriptors, ranging from "carcinogenic to humans" to "not likely to be carcinogenic to humans." The quantitative assessments also address noncancer and cancer health effects and are developed if there are sufficient credible research data, primarily from either animal (toxicity) or human (epidemiology) studies to support this type of analysis. The noncancer dose-response assessments may include

- an oral reference dose (RfD)—an estimate of the daily exposure to a chemical that is likely to be without an appreciable risk of deleterious effects during a person's lifetime—expressed in terms of milligrams per kilogram, and
- an inhalation reference concentration (RfC)—an estimate of the daily exposure to a chemical that is likely to be without an appreciable risk of deleterious effects during a person's lifetime—expressed in terms of milligrams per cubic meter.

The quantitative cancer toxicity assessments include estimates of a chemical's carcinogenic potency—a "cancer slope factor" and "unit risks." Both the cancer slope factor and unit risks are estimates of the increased

cancer risk (e.g., 1 in 100 people getting cancer, 1 in 1,000, 1 in 1 million, etc.) from a lifetime of exposure to a given chemical. However, the unit risk is an estimate of the increased risk for lifetime exposure at a standard concentration of a chemical in air or water (1 microgram per cubic meter of air or 1 microgram per liter in water), whereas the cancer slope factor is an estimate of the increased risk per unit dose (calculated using a dose-response curve, or a graph that shows the relationship between a dose and the proportion of exposed persons or animals that have a biologically significant response).[3]

Historically and currently, the focus of IRIS toxicity assessments has been on the potential health effects of long-term (chronic) exposure to chemicals. According to OMB,[4] EPA is the only federal agency that develops qualitative and quantitative assessments of both cancer and noncancer risks of exposure to chemicals, and EPA does so largely under the IRIS program. Other federal agencies develop qualitative cancer assessments or quantitative estimates of noncancer effects of exposure to chemicals in the environment. For example, the Agency for Toxic Substances and Disease Registry (ATSDR) develops quantitative estimates of the noncancer effects of exposures to chemicals in the environment for exposures of up to 14 days (acute); more than 14 days but less than a year (subchronic); and 365 days and longer (chronic). While ATSDR's toxicological profiles include information from other agencies' cancer assessments, including EPA's quantitative IRIS cancer assessments, ATSDR does not develop quantitative cancer assessments. ATSDR toxicological profiles also include qualitative cancer assessments developed by the Department of Health and Human Services' National Toxicology Program and the World Health Organization's International Agency for Research on Cancer (IARC). While these latter assessments provide information on the effects of long-term exposures to chemicals, they only provide qualitative assessments of cancer risks (e.g. known human carcinogen, likely human carcinogen, etc.) and not quantitative estimates of cancer potency, which are required to conduct quantitative risk assessments.

[3]The cancer slope factor and unit risk typically are both upper bound estimates (the plausible statistical upper limits of the true value of a quantity).

[4]OMB, Fiscal Year 2006 Program Assessment Rating Tool (PART) assessment of EPA's Human Health Risk Assessment Program.

As the IRIS database became more widely used and accepted, EPA took steps, beginning in the early 1990s, to improve and maintain the IRIS program and database. For example, the agency created an IRIS Quality Action Team that produced a report in 1994 outlining a number of recommendations for improvement, and EPA implemented a pilot program from 1995-1997 to test new operational procedures for the IRIS program. Changes under the pilot program included developing a standard toxicological review document to support each IRIS summary, incorporating peer review into the assessment process, and establishing a standing group of 18 senior health scientists to conduct the internal agency review of all IRIS draft assessments. The standing group, now called the IRIS Agency Review Committee, includes representatives from the program offices and regions. EPA also formed an IRIS implementation strategy team that developed recommendations in 1997 to improve the IRIS program and database. Key recommendations addressed the need to (1) update IRIS information, (2) establish an annual agenda for the program, (3) form a central IRIS staff to be responsible for the database and to coordinate with the program and regional offices leading individual IRIS assessments, (4) provide Internet access to the IRIS database, and (5) conduct more outreach to users.

In response, EPA formed a small centralized IRIS staff in the Office of Research and Development, National Center for Environmental Assessment (NCEA), which has implemented many of these recommendations. For example, EPA placed the IRIS database on its Web page, set up a hot line service to improve outreach with users, and started developing an annual IRIS agenda that identifies the chemicals to be assessed during the fiscal year (new and ongoing assessments) and providing this agenda to the public in a notice in the *Federal Register*. EPA also responded to the recommendations by posting external peer review drafts of IRIS assessments on EPA's Web page and considering public comments received on these drafts. As discussed below, EPA has continued to evaluate its IRIS assessment process and make changes in an effort to improve it.

EPA's Efforts to Improve the IRIS Assessment Program Have Not Produced the Desired Results

In response to criticisms and in an effort to meet the needs of the programs and entities that rely on IRIS information, EPA has continued to make a number of IRIS assessment process changes aimed at improving the timeliness, quality, consistency, and transparency of IRIS assessments. However, even with process changes and increased program funding and staffing, EPA has not been able to routinely complete credible assessments or decrease its backlog of ongoing assessments. Several key factors have contributed to EPA's inability to achieve a level of productivity that is needed to sustain the IRIS program and database, including the OMB/interagency review process managed by OMB, certain management decisions and issues regarding the IRIS program, and the compounding effect of delays. In addition, because the OMB/interagency review process is not transparent, this change also limits the credibility of IRIS assessments.

EPA Efforts to Improve IRIS Continue

Despite the many steps that EPA took throughout the 1990s aimed at improving the IRIS assessment process, the agency has continued to face criticism that the risk information in the database is outdated and of varying quality. For example, according to congressional testimony in 2000 by a risk assessment expert and a representative of a chemical industry association, the outdated and inconsistent information in IRIS represented a serious limitation that undermined the accuracy of risk assessments and risk management decisions. In addition, external parties—notably entities that may be affected by the IRIS assessments, including other federal agencies and industry—have criticized the IRIS assessment process as lacking transparency and have sought earlier input into EPA's assessment process. Further, as a result of continuing concerns that EPA and state regulators were relying on scientific information that was potentially outdated, in 2000, a Senate appropriations committee report directed EPA to conduct an assessment to determine the need to both update and add new assessments to IRIS.

In response to the criticisms and in an effort to meet the needs of the programs and entities that rely on IRIS information, EPA has continued to make a number of IRIS assessment process changes aimed at improving the timeliness, quality, consistency, and transparency of IRIS assessments. For example, EPA further centralized the assessment process, hiring additional scientists in the Office of Research and Development to lead individual IRIS assessments; in the past, chemical managers in various program offices and regions had led the assessments on a voluntary basis. EPA made this change to improve the timeliness of assessments and to address concerns about the inconsistency of assessments that the

different offices were producing. In addition, EPA changed its peer review requirements, opting for peer review panels, whose meetings the agency has opened to the public, rather than obtaining written peer review comments from several experts. According to EPA, these steps were taken to provide the best possible scientific review of each assessment and to make the review process more transparent.

EPA also decided to conduct its internal agency review of assessment drafts earlier in the process. That is, the 18-member IRIS Agency Review Committee comprising EPA senior health scientists now comments on draft assessments before they are released for external review, as well as after external review comments are incorporated in the assessments. In the past, the review by the IRIS Agency Review Committee had taken place once, following the external reviews. According to EPA, this change was made to enhance peer reviews by identifying key science issues and providing external reviewers with drafts that had already been thoroughly vetted within EPA. Prior to this change, IRIS assessments had been internally peer reviewed by three or four scientists with relevant expertise in the Office of Research and Development, program offices, or regions before the assessments were sent to external peer review.[5] EPA has also added formal briefings of draft assessments to the Assistant Administrator, Office of Research and Development, at various stages in the assessment process. In addition, EPA informally elevated final IRIS assessment approval authority to the Assistant Administrator, Office of Research and Development. EPA has also delayed or suspended some assessments to await new or scientific studies.

Another key change that EPA has incorporated into the IRIS assessment process at OMB's request is an OMB/interagency review process that is managed by OMB. The purpose of these reviews is to obtain input from OMB and other federal agencies that OMB has determined have an interest in particular IRIS assessments as they are being developed in order to help ensure and increase their quality. The reviews occur at two points in the IRIS assessment process—first, after the internal agency review but before the external peer review; and second, after EPA has incorporated input from the external peer review. According to EPA officials, this OMB/interagency review process has evolved from an ad hoc review of selected IRIS assessments of interest to OMB and other federal agencies to a process that now requires, for all assessments, OMB's determination that

[5]This internal peer review continues to be conducted during the assessment drafting stage.

EPA has satisfactorily addressed all OMB/interagency comments. This determination must be made both before EPA can provide draft assessments to external peer reviews and before EPA can finalize and post assessments on the IRIS database.

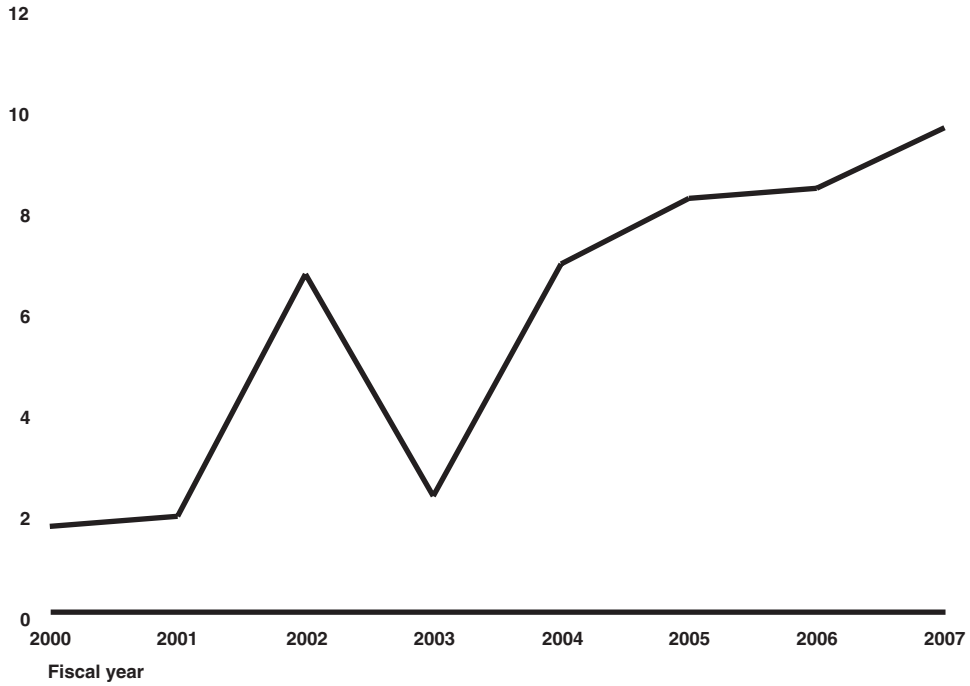
Although the IRIS assessment process continues to evolve, it currently typically includes the following steps (see app. II for a flow chart of the process):

- solicitation of chemical nominations from EPA program and regional offices, federal agencies, and the public.
- selection of chemicals to be assessed during the fiscal year (referred to as the annual agenda).
- publication of a *Federal Register* notice announcing EPA's annual agenda—the specific chemical assessments the agency intends to conduct—and requesting scientific information about these chemicals, thereby giving the public and other federal agencies an opportunity to identify relevant studies.
- a review of the scientific literature.
- development of draft IRIS toxicological reviews and summaries containing qualitative and, if sufficient information is available, quantitative risk estimates, that have undergone internal peer consultation—a peer review by three or four EPA scientists with relevant expertise.
- initial internal agency review, which includes review and comment from the 18-member EPA IRIS Agency Review Committee.
- OMB/interagency review by other federal agencies, such as DOD, DOE, and NASA, coordinated by the Office of Management and Budget; OMB informs EPA when EPA has adequately addressed interagency comments.
- external peer review by a group of independent experts, convened by an EPA contractor, the Science Advisory Board, or the National Academies, and public comment.
- a second internal agency review.
- a second OMB/interagency review; OMB informs EPA when EPA has adequately addressed interagency comments.

- EPA management review and approval.
- posting of IRIS assessments on the IRIS database, available on EPA's Web site.

In addition to EPA continuing to revise its IRIS assessment process, since fiscal year 2000, funding for the IRIS program has increased—from $1.7 million to $9.6 million in fiscal year 2007 (see fig. 2). The need for increased resources to accomplish significant IRIS improvements had been noted in the February 1997 IRIS Implementation Strategy Team Report.

Figure 2: Funding for the IRIS Program, Fiscal Years 2000-2007



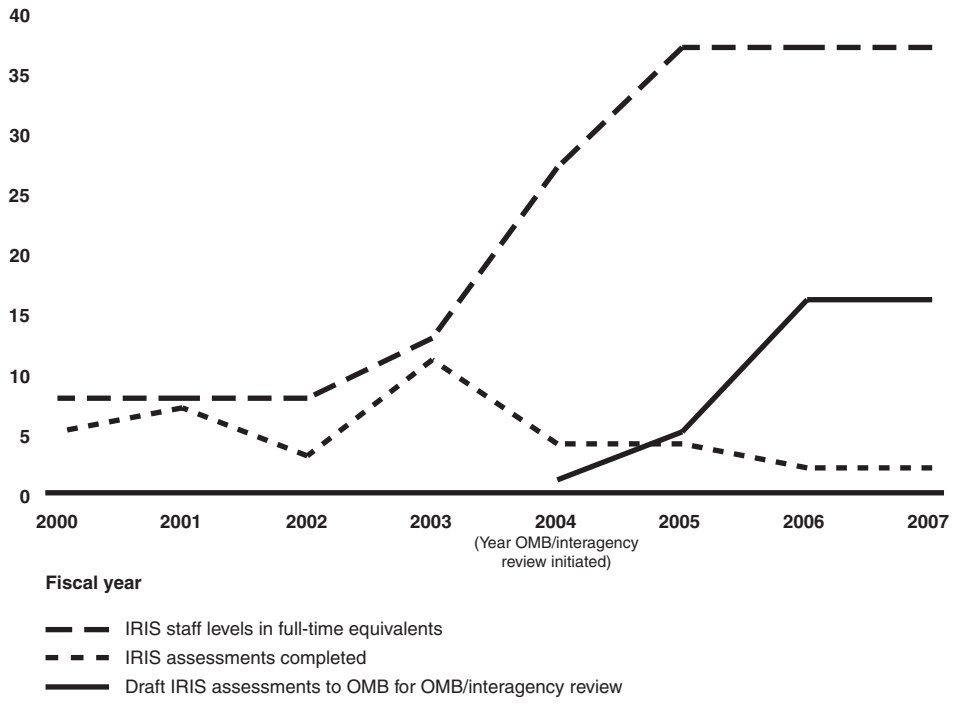
Source: GAO analysis of EPA data.

Note: In fiscal year 2002, a congressional appropriations conference committee designated $5 million to accelerate the development of new IRIS values and to update current IRIS values. According to EPA officials, this funding was provided to various EPA program offices to support the IRIS assessments that program offices were leading at that time. In addition, EPA has reprogrammed funds from some of its other programs to expand the IRIS program to support the development of IRIS assessments, especially high-priority chemicals.

Process Changes and Increased Resources Have Not Enabled EPA to Routinely Complete IRIS Assessments and Meet Users' Needs

As shown in figure 3, EPA has continued to take steps to improve the IRIS assessment process and increased program funding and staffing, but the agency has not made progress in completing IRIS assessments and reducing its backlog of ongoing assessments. Although the number of program staff has quadrupled from 8 to 37 between 2000 and 2007, EPA has, on average, completed about five IRIS assessments per year—and in fiscal years 2006 and 2007, completed only two each year. However, EPA sent 16 draft assessments to OMB for OMB/interagency review in both fiscal years 2006 and 2007 and plans to provide 16 draft assessments to OMB annually in fiscal years 2008 through 2012. Further, in its fiscal year 2008 budget justification documents, EPA said it plans to complete 8 IRIS assessments in fiscal year 2008, noting that completion of assessments, rather than providing drafts to OMB, is the most important outcome.

Figure 3: Number of Completed IRIS Assessments, Draft Assessments to OMB, and IRIS Staff in Full-Time Equivalents, Fiscal Years 2000-2007



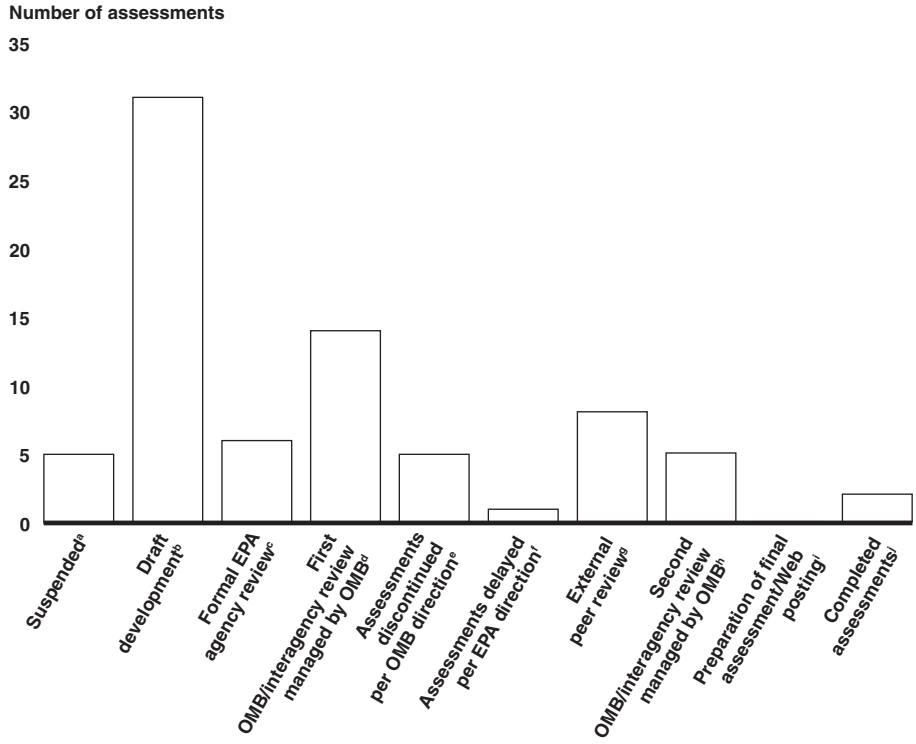
Source: GAO analysis of EPA data.

During fiscal year 2007, EPA had 77 ongoing IRIS assessments. As of December 1, 2007, 70 of these were still in progress—2 were completed in fiscal year 2007 and 5 were discontinued at the direction of OMB.[6] Representing EPA's first efforts to develop IRIS assessments covering acute (short-term) exposure to chemicals, EPA initiated them in 2004 to meet EPA program needs, including, for example, to help it implement the Clean Air Act. In November 2007, EPA officials told the members of the Board of Scientific Counselors committee evaluating EPA's health risk assessment program that OMB did not explain to EPA why it was directing the agency to terminate these IRIS assessments.

Of the 70 assessments still in progress as of December 1, 2007, 48 have been in progress for more than 5 years, and 12 of those for more than 9 years. As figure 4 shows, many of these assessments are either being drafted or are undergoing internal agency review. Additionally, 19 assessments are undergoing one of the two OMB/interagency reviews managed by OMB, and 5 of the assessments have been suspended by EPA for various reasons, including waiting for new research studies that have yet to be completed.

[6]OMB did not include these five assessments towards EPA's fiscal year 2006 annual performance goals and thus does not acknowledge that EPA sent 16 draft assessments to it for OMB/interagency review that fiscal year.

Figure 4: December 2007 Status of IRIS Assessments That EPA Reported as Ongoing in Fiscal Year 2007



Source: GAO analysis of EPA information.

[a]EPA has suspended five IRIS assessments for several reasons, including waiting for additional research, reevaluating the need for an assessment, and potentially broadening the scope of an assessment.

[b]This phase includes conducting literature searches, drafting assessments, and incorporating comments from an internal peer review process; it is concluded when the IRIS Program Director provides the draft and support documents for review by EPA's IRIS Agency Review Committee.

[c]This phase includes the review by EPA's IRIS Agency Review Committee and revisions in response to the review; it is concluded when the NCEA Associate Director for Health transmits a draft to OMB.

[d]This phase encompasses the first OMB/interagency review managed by OMB; revisions in response to the review; negotiations among EPA, OMB, and other federal agencies over changes to the draft and the content of the charge questions for the external peer reviewers; and briefing of the Assistant Administrator for the Office of Research and Development (ORD). It is concluded when OMB informs EPA that issues have been resolved and the assessment can proceed to the next step—external peer review.

[e]In November 2007, EPA said that in 2006 OMB requested and then in 2007 directed EPA to discontinue the five IRIS assessments covering acute exposures that EPA had sent to OMB for OMB/interagency review from July to September 2006.

[f]One assessment has been delayed by EPA for almost 2 years pending the development of an acceptable uncertainty analysis.

[g]This phase encompasses public review and comment, the external peer review conducted by an independent panel, and incorporation of draft revisions in response to peer review and public comments. It is concluded when the NCEA Associate Director for Health transmits a revised draft to OMB for the second OMB/interagency review it manages.

[h]This phase encompasses the second review by EPA's IRIS Agency Review Committee; the second OMB/interagency review managed by OMB; revisions in response to comments received from agency and OMB/interagency review; negotiations among EPA, OMB, and the other federal agencies over changes; and briefing of the Assistant Administrator for ORD. It is concluded when ORD, the IRIS Agency Review Committee, and other federal agencies resolve all issues, OMB informs EPA that issues have been resolved, and a revised IRIS assessment is sent for preparation of a final IRIS assessment.

[i]This phase encompasses the final preparation of the IRIS summary and toxicological review and the review and clearance by the NCEA Director. It is concluded when the assessment is posted on the IRIS Web site after the Assistant Administrator, ORD, approves a fact sheet about the assessment prepared by the chemical manager.

[j]EPA completed two assessments in July and September 2007.

In addition to the current backlog of 70 ongoing and suspended IRIS assessments, EPA data from 2001 through 2003 indicated that 287 of the chemicals in the IRIS database may potentially need to be updated. Specifically, EPA reviewed the scientific literature on the 460 chemicals in the database not being reassessed to identify assessments that may need to be updated in light of new studies or information that could potentially change the risk estimates currently in the IRIS assessments. In addition, while conducting these literature reviews, EPA identified new studies or information that would enable the agency to develop additional risk estimates (e.g., add an estimate, such as an RfD or cancer potency estimate, for assessments lacking such estimates). EPA's "screening level review" found new information that could potentially (1) change an existing risk estimate for 169 chemicals and/or (2) allow EPA to develop additional risk estimates for 210 chemicals. Although EPA identified these chemicals as candidates for reassessment, as of fiscal year 2007, the agency had initiated reassessments of only a few of these chemicals. Further, because the screening levels were completed more than 4 years ago, it is likely that more assessments may now be outdated.

EPA officials said they have initiated another screening level review that they expect to be completed by July 2008. Importantly, in its performance assessment of EPA's human health risk assessment program, which includes IRIS, OMB considers health assessment values in IRIS as out of date if they were developed more than 10 years ago and where new scientific information has been identified that could change the health assessment value. This designation highlights the need for EPA to become productive in completing its IRIS assessments if it is to remain a viable and credible assessment resource. We note that EPA recently formed a new working group that will specifically address chemical assessments that are

over 10 years old and for which new information is available. This group's efforts are currently in the planning stages, and an EPA official involved in this group indicated that the agency expects to begin work on this effort by March 2008.

Although EPA has stated its intent that the IRIS database be updated and expanded to include new assessments requested by IRIS users as soon as "practically possible," the current backlog continues to present a practical impediment to doing so. Because of the backlog, for example, EPA did not initiate new assessments in fiscal years 2006 and 2007.[7] In fact, key IRIS users—two EPA program offices—specifically requested that the IRIS program management focus its resources on expediting the completion of ongoing IRIS assessments important to their regulatory and cleanup responsibilities rather than initiating new assessments in fiscal year 2007. For example, the Office of Solid Waste and Emergency Response identified 29 assessments that were important to that office and asked EPA to finish these IRIS assessments before initiating others. In addition, the Office of Air identified 28 high-priority IRIS assessments that it needed to fulfill its regulatory mandates,[8] 14 of which it identified as being of the "highest priority" and the other as "high priority;" IRIS reviews for 12 of the chemicals of highest priority are in progress, but most of these assessments are still either being drafted or are undergoing an internal agency review. In terms of new assessments that will be needed for EPA's air toxics program, an official in the Office of Air and Radiation said there were about 12 to 20 air toxics of concern nationwide for which IRIS risk information is needed and about 50 or so uncommon air toxics emitted in isolated "hot spots" (e.g., near a chemical plant in sparsely populated areas) where a small number of people who live nearby—perhaps 200 or so—are exposed to relatively high doses of these air toxics. He said it is more difficult to get approval for assessments of such chemicals because of the small number of people potentially affected, even though these chemicals may be very harmful to human health and the environment.

[7]EPA has, in some cases, divided an ongoing assessment into two assessments. For example, in fiscal year 2007, the arsenic assessment covering both cancer and noncancer risks, which was started in 2003, was divided into two separate assessments. Although the noncancer assessment was started in 2003, IRIS Track, which tracks the status of ongoing assessments, shows a 2007 start date for the IRIS noncancer assessment.

[8]The two offices identified the same priority chemicals in eight cases.

Moreover, as discussed above, EPA program offices and state and local entities have identified needs for assessments of hundreds of chemicals not yet in IRIS. For example, in its 2003 needs assessment report, EPA reported that about half of the chemicals and chemical classes that IRIS users had nominated for assessment were not included in IRIS.[9] Reasons that IRIS users nominated these chemicals included to support anticipated rule making, to support agency or state implementation priorities, to address children's health concerns, and to address the widespread occurrence of a chemical at contaminated sites and in groundwater. Unmet IRIS needs affect IRIS data users both within and outside EPA. For example, EPA's Office of Research and Development noted in its 2003 *Air Toxics Multi-Year Plan* that quantitative assessment values (for noncancer and cancer health effects) for many high-priority air toxics that are needed to support site-specific efforts and regulatory decisions are "missing." Along these same lines, in its *Office of Solid Waste Integrated Research and Development Plan for the Hazardous Waste Identification Rule*, EPA's Office of Research and Development identified 460 chemicals of potential concern and reported that roughly 200 of these lack quantitative assessment values (estimates of the risk of cancer and noncancer effects of the chemicals). Non-EPA users also are affected by the lack of IRIS values. According to the preliminary results of an EPA project aimed at determining how IRIS is used by non-EPA decision makers,[10] non-EPA users have one primary criticism regarding IRIS—they are frustrated by the lack of new assessments, particularly for "controversial" chemicals. These users reported that the absence of an IRIS assessment creates enormous challenges for state regulatory agencies and significant uncertainty for regulatory parties.

Although EPA's 2003 needs assessment report had identified a potential need to complete 50 IRIS assessments annually to meet user needs, the agency has not finalized more than 11 assessments a year during the past 10 years. As figure 3 shows, productivity has, in fact, declined since 2003, with EPA completing 4 assessments in fiscal year 2005 and 2 each in fiscal years 2006 and 2007. EPA's updated multiyear plan estimates incremental increases in the number of IRIS assessments EPA will complete in fiscal years 2008 through 2011, at which point EPA's annual goal is to complete

[9]The other nominations were for chemicals in IRIS with outdated assessments.

[10]The preliminary findings of the Use of IRIS Project were presented during the EPA's Board of Scientific Counselors' Human Health Risk Assessment Subcommittee meeting on November 15, 2007.

16 IRIS assessments.[11] We note that even if EPA were to overcome the significant productivity difficulties it has experienced in recent years and meet this goal of completing 16 assessments a year beginning in 2011, it is not clear that this level of productivity would meet the needs of EPA program offices and other users, given the current status of the database. For example, in November 2007, the Deputy Administrator of EPA's Region 2 told the Board of Scientific Counselors panel reviewing EPA's human health risk assessment program that even 16 IRIS assessments per year would not meet their chemical assessment needs. Although funding for the IRIS program has increased since 2000, we note that fiscal year 2007 funding of $9.6 million represents approximately 0.1 percent of EPA's $7.3 billion annual budget.

It is a positive step that EPA delivered 32 IRIS assessments to OMB for OMB/interagency review in fiscal years 2006 and 2007. However, in general, the IRIS assessments sent to OMB during this period were on less controversial chemicals. In its December 2005 multiyear plan, EPA specified 10 major assessments that would be sent for external review in fiscal years 2006 and 2007. As of December 1, 2007, only 2 of these assessments had been sent for OMB/interagency review.[12] In order to meet user needs and therefore enable EPA to more effectively protect public health, it will be important for EPA to make progress on the assessments of the more controversial chemicals, which tend to be those to which people are more widely exposed.

Lastly, while EPA's assessment process changes have resulted in EPA providing the public with more information about IRIS assessments, some of the information provided in *Federal Register* notices and in the IRIS database itself is not accurate or is incomplete. For example, some assessments that have been suspended have continued to be identified as ongoing, and information on the status of the individual assessments provided in a system called IRIS Track has not been kept up to date. Regarding this latter point, we found that more EPA chemical managers started updating this database as a result of our review. Nonetheless, some

[11]EPA, *Human Health Risk Assessment Multi-Year Plan* (Washington, D.C., 2007).

[12]In its 2005 multiyear plan EPA, specified that it would send the assessments for acrylamide, MTBE, naphthalene, tetrachloroethylene (perc), acrylonitrile, formaldehyde, methanol, methylene chloride, trichloroethylene, and dioxin for external review during fiscal years 2006 and 2007. Only acrylamide and tetrachloroethylene (perc) have been sent to OMB for OMB/interagency review.

of the milestone estimates remained outdated, and the milestones in IRIS Track did not reflect the current assessment process. We note that in November 2007, EPA created a new IRIS Web page, updating and consolidating some of the milestones to better reflect the current process. However, two key milestones—the second OMB/interagency and EPA internal agency reviews—are still not identified.

EPA's Productivity Problems Stem from Several Key Factors

In our view, several key factors have contributed to EPA's inability to achieve a level of productivity that is needed to sustain the IRIS program and database. These factors that have hindered EPA's efforts to improve productivity are

- the OMB/interagency review process managed by OMB,
- the growing complexity and scope of risk assessments,
- certain management decisions and issues regarding the IRIS program,
- congressional action that has delayed some assessments with potentially significant economic effects, and
- the compounding effect of delays.

OMB/Interagency Review Process

One factor that has made it more difficult for EPA to complete IRIS assessments in a timely manner is the OMB-managed interagency review process, initiated in 2004 at OMB's direction. According to OMB, the purpose of OMB/interagency reviews is to ensure that federal agencies are aware of draft IRIS assessments in which they have an interest and that these agencies have the opportunity to be involved with the IRIS assessments as they are being developed in order to help ensure and increase their quality. This process, initially conducted on an ad hoc basis, was put in place in response to interagency conflicts that EPA faced when it attempted to finalize some IRIS assessments for chemicals that became highly controversial, such as perchlorate, naphthalene, and TCE—chemicals that are or have been considered by some federal agencies, including DOD, DOE, and NASA, to be integral to their missions. Notably, EPA's IRIS assessments of these chemicals could lead to regulatory actions that could, among other things, restrict the use of these chemicals, require agencies to provide protective gear to their employees exposed to the chemicals at work, or require agencies or their contractors to carry out or pay for cleanup of contamination at federal sites. The interagency conflicts about these IRIS assessments have contributed to their delays—

resulting, for example, in EPA having to essentially restart the naphthalene assessment after it had been drafted and peer reviewed.

The OMB/interagency review process has evolved over time, but it remains an informal process with OMB generally communicating its review requirements verbally. OMB has not provided EPA with written guidance, directives, policies, or procedures on this significant review program. In 2005, OMB started requiring EPA to send OMB all draft IRIS assessments for an OMB/interagency review before the assessments are provided to external peer review panels. In addition, OMB requires EPA to send the assessments to OMB a second time, after EPA has addressed the external peer review comments and recommendations. According to EPA officials, in 2007, OMB informed EPA that it cannot send its draft assessments for external peer review or post final EPA assessments on the EPA IRIS database until OMB verbally informs EPA that it has satisfactorily addressed OMB/interagency comments. OMB has not specified which authority or authorities it is using to review IRIS assessments. Because IRIS assessments are not regulations, they are not covered by Executive Order 12866 which provides for OMB review of proposed regulations, among other things. In addition, although in January 2007, Executive Order 13422 amended Executive Order 12866 by establishing a role for OMB in reviewing "significant guidance" documents, which could potentially include IRIS assessments, OMB officials told us that OMB has not formally classified IRIS assessments as significant guidance documents within the meaning of this executive order.[13] These officials said that OMB had the authority to review IRIS assessments prior to the issuance of Executive Order 13422 and was continuing to use this general authority. We note that these executive orders address only OMB's reviews of two specific categories of agency documents and that OMB has not identified IRIS assessments as falling into either of these categories.

[13]Under the executive order, significant guidance is defined as, "a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to (1) lead to an annual effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees or loan programs or the rights or obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order."

Under the OMB/interagency review process for IRIS assessments, OMB identifies the federal agencies from which it will seek comments on the assessments and provides comments and questions to EPA from OMB and the other federal agencies. EPA then revises the assessments to address the comments and questions and also provides OMB with a document discussing how it has addressed each of the issues raised. According to EPA officials, this step is concluded when OMB verbally informs EPA that all of the issues are resolved. Thus, before EPA can provide its draft assessments to external peer reviewers, EPA, OMB, and the other federal agencies must reach agreement on (1) EPA's revised IRIS assessment and (2) the scope of the external peer review, including specific questions reviewers will be asked.

The OMB reviews have primarily been conducted by a policy analyst in the Office of Information and Regulatory Affairs who, according to OMB officials, has a toxicology background and is qualified to conduct these reviews. If EPA does not agree with some of the proposed changes or peer review requirements, OMB officials said the assessment could be elevated to higher management levels within EPA for resolution. Thus, the framework of the OMB/interagency review process can essentially give more weight to OMB and the other federal agencies than to EPA chemical managers who have prepared the assessments and the many scientists and experts who have peer reviewed them. Further, in commenting on OMB's proposed risk assessment bulletin in 2007, the National Academies stated its concern that scientific issues may be superseded by policy considerations to the extent that the technical aspects of risk assessments would be overseen by OMB and not by the peer review process or by agency technical managers. Similarly, an EPA official noted that the farther removed the scientists and experts who have prepared or peer reviewed the assessments are from the negotiations and decisions over assessment changes requested by OMB and other federal agencies, the decisions are based more on political rather than scientific considerations.

According to EPA officials, some of the OMB/interagency reviews have provided valuable input. However, they said the reviews have also added a significant amount of time to the assessment process, in part because the reviews are not subject to any specific time frames or deadlines and because responding to OMB comments in some cases has required several iterations to address nonsubstantive issues involving minor clarifications, semantics, and organization. (We note that according to the executive order under which OMB reviews regulatory actions, OMB must generally complete such reviews within 90 days.) In terms of time frames, our analysis of EPA data as of December 1, 2007, indicate that of the 36

assessments sent to OMB for the first OMB/interagency review, 16 have completed this process. While 4 completed the process in less than 6 months, 12 of them were in the review process for 6 or more months. Moreover, five additional assessments—the previously discussed assessments of acute exposure—were discontinued at the direction of OMB after a year in the OMB/interagency review stage.

In addition, as of December 1, 2007, 5 of 10 draft assessments had completed the second OMB/interagency review, which OMB officials said is conducted by OMB to ensure that EPA has adequately considered the comments from external peer review panels. These assessments were at the second OMB/interagency review stage for periods ranging from 10 days to almost 4 months. According to EPA, while agencies should only point out major scientific issues that would warrant halting the release of the assessment, some comments submitted to them from the second OMB/interagency reviews by OMB have gone beyond their intended purpose of identifying only major scientific concerns and thus have unnecessarily added time to the assessment process. (See app. III for additional information about the time frames for the OMB/interagency reviews.) Further, EPA officials noted that the OMB/interagency review process can delay not only the IRIS assessments undergoing OMB/interagency review but also the other assessments that the EPA chemical managers would be working on or starting if they were not engaged in responding to the OMB/interagency comments.

Overall, the two OMB/interagency reviews managed by OMB have introduced a significant level of uncertainty into the time frames for completing IRIS assessments. This fact was reflected in EPA's December 2005 *Human Health Risk Assessment Multi-Year Plan*, which identified EPA's annual performance goals for fiscal years 2006 through 2012. The goals did not include the number of IRIS assessments completed and posted on the IRIS Web page—the performance goal that would be expected—but instead the number of assessments provided to OMB for the first OMB/interagency review. While EPA's annual performance goal for IRIS assessments had been the number of completed assessments, during the Program Assessment Rating Tool (PART) review by OMB, it was agreed that the number of assessments provided to OMB for OMB/interagency review was the most appropriate annual measure of performance because EPA "relinquishes direct control of production dates" when it sends draft IRIS assessments to OMB.

In addition to adding time to the IRIS assessment process, the OMB/interagency review process also affects the credibility of

assessments primarily because the review process lacks transparency. According to EPA's *Risk Characterization Policy and Handbook*, the risk assessment process—which includes the hazard identification and dose-response analysis that constitutes IRIS assessments—should be transparent and its products should be clear, consistent, and reasonable. Transparency is particularly important in cases such as this when potentially affected parties are providing input into, and in some cases questioning, EPA's scientific analyses supporting its IRIS assessments. Specifically, a transparent process allowing IRIS users and the public to see the comments from OMB and other federal agencies—including those potentially impacted by the IRIS assessments—as well as EPA's responses to them, could help alleviate concerns about potential bias in the assessments.

However, under the OMB/interagency review process managed by OMB, the comments EPA receives from OMB and other federal agencies and EPA's responses to them are not available to the public. OMB does not authorize their disclosure to the public on the basis that these communications are internal deliberations of the executive branch. Overall, because the rationale for changes to EPA's scientific assessments stemming from OMB and the interagency review process are not disclosed, the credibility of the IRIS assessments is reduced. We note that the former Assistant Administrator for the Office of Research and Development has emphasized the importance of transparency in the IRIS assessment process. Specifically, he stated that the best cure for controversy surrounding IRIS assessments "is early and frequent visits to the experts, second opinions, and lots of sunshine" (that is, transparency).

Growing Complexity of Risk Assessments and Risk Assessment Methods and Models

Another factor that affects the length of time it takes to complete IRIS assessments is the growing scientific complexity of the assessments. For example, according to John Graham, the former director of both Harvard's Center for Risk Analysis and OMB's Office of Information and Regulatory Affairs, more and different types of scientific data have made the IRIS assessment of health effects more challenging.[14] As a result, EPA chemical managers and scientists need to explore new methods of analyses and evaluate a wider variety of potential health effects (e.g., multiple disease endpoints) than in the past. In addition, chemical managers responsible for the assessments are working with a growing body of complex risk

[14]Examples cited by the former director include scientific data such as subtle biologic changes, biomarkers, and partial data on one or more mechanistic hypotheses.

assessment guidelines, such as EPA's 2005 *Guidelines for Carcinogen Risk Assessment* (final revised cancer assessment guidelines) and its supplement relating to children, *Supplemental Guidance for Assessing Susceptibility from Early Life to Exposure to Carcinogens*. In addition, chemical managers must increasingly analyze studies using state-of-the-art physiologically based pharmacokinetic (PBPK) models, which improve the estimation of doses across species and routes of exposure and provide insights on uncertainty.[15] Before EPA relies on PBPK models intended for risk assessments, the agency needs to evaluate them. Such evaluations include a review of the model purpose, structure, mathematical representation, parameter estimation (calibration), and computer implementation. EPA has established criteria for acceptance of a PBPK model for risk assessment purposes in one of two detailed reports issued in 2006, *Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment*. The other 2006 report on PBPK models is the *Use of Physiologically Based Pharmacokinetic (PBPK) Models to Quantify the Impact of Human Age and Interindividual Differences in Physiology and Biochemistry Pertinent to Risk*. In fiscal years 2008 and 2010, EPA plans to issue additional information on PBPK modeling for use in risk assessments.

The chemical managers are also called upon to use some new methods and models of risk assessment that are being developed or being applied for the first time in the absence of guidelines. For example, uncertainty analysis is a method in the early stages of development and use in risks assessments, for which EPA has not yet developed guidance.[16] However, chemical managers are having to develop and apply new approaches to quantify and communicate uncertainty. According to EPA, these approaches include identifying alternative studies and endpoints for the application of uncertainty factors in noncancer risk assessment and the application of alternative dose-response models for cancer risk assessment. Important cutting-edge assessment models relevant to IRIS assessments include biologically based dose-response models, which are

[15]Examples of PBPK model applications in risk assessments include interspecies extrapolation of the dose-response relationship, route-to-route extrapolation, estimation of response from varying exposure conditions, estimation of human variability (within the whole population or subpopulations), and high-to-low dose extrapolation.

[16]EPA plans to release draft reports in 2010 on methods for analyzing and characterizing uncertainty in hazard and dose response and in PBPK models.

based on the modes of action of chemicals—that is, analysis of physiological, chemical, and biological information that helps identify a chemical agent's role in the development of tumors. These highly complex models can analyze multiple modes of action and can be responsive to EPA's 2005 guidelines for cancer assessment that emphasize mode-of-action evaluation. According to EPA, the agency has extensive experience in qualitative mode-of-action analysis but more limited experience in the quantitative evaluation of multiple modes of action.

EPA Management Decisions and Issues

Some of the IRIS assessment process changes that EPA management has implemented in recent years have made it more difficult for the agency to complete assessments in a timely manner. These changes were aimed primarily at improving the quality of the assessments. It is too early to determine whether or to what extent the changes have enhanced the scientific credibility of the assessments,[17] but it is clear they have contributed to assessment delays overall. Changes that have affected the time frames for IRIS assessments include waiting for additional scientific studies to be completed, waiting for the development of an acceptable methodology for presenting qualitative and quantitative uncertainty analysis in the IRIS assessments, and numerous process changes.

Waiting for additional scientific studies: EPA management's decision in some cases to suspend ongoing IRIS assessments while waiting for additional scientific studies to be completed has contributed to EPA's lack of productivity. According to a former IRIS program director, EPA's general approach in the 1990s was to use only information from completed scientific studies available at the time of the assessment—e.g., the reviews were based on the best available science. However, EPA has awaited the results of new and ongoing studies before completing some IRIS assessments, which has resulted in delaying them for years. Examples of key chemical assessments that have been delayed while EPA waits for new studies include those for formaldehyde and Royal Demolition Explosive,[18] discussed later. Other delayed assessments include those for tetrahydrofuran, perfluorooctane sulfonate-potassium salt (PFOS), and

[17]According to an EPA official, the November 2007 review of the IRIS program by the Board of Scientific Counselors, an independent board of experts appointed by EPA to assess its program, concluded that the program "met expectations." A report covering this review, which included evaluating the scientific quality of IRIS assessments, is expected in early 2008.

[18]Also referred to as RDX or hexahydro-1,3,5-trinitrotriazine.

perfluorooctanoic acid-ammonium salt (PFOA). We understand that there may be exceptional circumstances for which it may be appropriate to wait for the results of an important ongoing study, such as a major epidemiological study that will provide new, critical data for an assessment. According to EPA officials, this is the case with research they are awaiting for its IRIS assessment of asbestos. However, as a general rule, requiring that IRIS assessments be based on the best science available at the time of the assessment, as had been the prior practice, is a standard that would best support a goal of completing assessments within reasonable time periods and minimizing the need to conduct significant levels of rework.

Developing an acceptable uncertainty analysis for IRIS assessments: Another management decision that has delayed the completion of IRIS assessments is to incorporate comprehensive uncertainty analysis into the IRIS assessments. Peer reviews of EPA's assessments by the National Academies and others have sometimes recommended additional uncertainty analysis; the Assistant Administrator, Office of Research and Development, has made the inclusion of qualitative and quantitative uncertainty analyses in IRIS assessments a high priority to, among other things, support better decisions and guide EPA's research agenda. Such analyses require the use of state-of-the-art tools to quantify uncertainty. That is, comprehensive—and, in particular, quantified—uncertainty analysis, is an emerging analytic tool. For example, EPA's August 2007 *Human Health Risk Assessment Multi-Year Plan* estimates releasing an external review draft report on methods for analyzing and characterizing uncertainty in hazard and dose-response assessments in 2010; the plan—which covers 2006 through 2012—does not estimate a final report date for this important guidance on uncertainty analysis. In the interim, EPA chemical managers have had to try to develop complex uncertainty estimates in draft assessments in the absence of agency guidance or protocols. As discussed later, this requirement has delayed the completion of an important assessment (tetrachloroethylene) for almost two years. Moreover, because EPA is now requiring all IRIS assessments to include basic or enhanced uncertainty analysis, other significant assessments that have been drafted have also been delayed, pending approval by the Assistant Administrator, Office of Research and Development, of an acceptable template for uncertainty analysis for significant assessments. Further, external peer reviewers of IRIS assessments containing quantified uncertainty analyses will need to have specialized expertise to assess the quality and reliability of these cutting-edge analyses—which themselves contain uncertainties and incorporate numerous assumptions. Evaluating the uncertainty assessments will be

challenging, given their complexities and the lack of guidance on this emerging method. Along these lines, members of the Board of Scientific Counselors[19] have questioned whether expert peer reviewers of EPA's IRIS assessments will have the necessary expertise in this emerging method. Finally, effectively communicating the results of complex uncertainty analyses may be challenging—in fact, some have questioned whether highly detailed quantitative uncertainty analysis enhances the values of risk assessments. For example, in commenting on a proposed OMB bulletin that would have provided risk assessment guidance to federal agencies, the Department of Health and Human Services noted that "characterization of every possible uncertainty or extensive evaluation of each assumption . . . could result in a confusing, less straight-forward document . . . that would not serve the public or the risk assessment community well."[20] Similarly, in its review of the proposed bulletin, the National Academies concluded that "there is a serious danger that agencies will produce ranges of meaningless and confusing risk estimates, which could result in risk assessments of reduced rather than enhanced quality and objectivity."

Continuous process changes, outdated standard operating procedures, and management issues: EPA's continual changes to the IRIS assessment process present a challenge to the chemical managers who are undertaking the assessments. Further, a number of changes have been implemented informally since the last update to the agency's standard operating procedures for fiscal year 2006 reviews. According to EPA, these changes have been made in order to continually improve the assessment process and to respond to changing requirements, such as the OMB-managed OMB/interagency review and the need to incorporate

[19]The Board of Scientific Counselors is a federal advisory committee established by EPA to provide advice, information, and recommendations about the Office of Research and Development's research program.

[20]OMB recently proposed a bulletin that would have provided risk assessment guidance to federal agencies. The proposed bulletin stated that "every quantitative risk assessment should provide a range of plausible risk estimates when there is scientific uncertainty or variability." OMB decided not to finalize the bulletin after a National Academies' committee severely criticized it, noting, among other shortcomings, that "the description of uncertainty and variability in the bulletin is oversimplified and does not recognize the complexities of different types of risk assessments or the need to tailor uncertainty analysis to a given agency's particular needs." In particular, the committee noted that "a central estimate and a risk range might be misleading in situations when sensitive populations are of primary concern." National Academies, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget Committee to Review the OMB Risk Assessment Bulletin* (Washington, D.C., 2007).

emerging risk assessment methods. Chemical managers have told us that there is much confusion about the process, including who needs to be briefed on the draft assessments and who has approval authority to move an assessment to the next step. In fact, in the absence of current operating procedures to guide chemical managers on basic procedures and program management responsibilities for the development, review, and finalization of IRIS assessments, EPA chemical managers recently took the initiative to develop a detailed graphic providing their best understanding of the process. One aspect of the IRIS assessment process that has become particularly unclear is the steps required to obtain approvals to move draft assessments through various stages (e.g., to OMB, external peer review, or final issuance). For example, until 2004, EPA used an agencywide consensus process to reach either unanimous or substantial agreement on draft assessments among members of the IRIS Agency Review Committee; if agreement could not be reached by the committee, the operating procedures had provided a detailed process for resolving contentious issues. When EPA moved from the consensus approach to an "agency resolution" approach, however, the guidance said only that final decisions on any contentious issues were to be resolved by either the NCEA Director or the Agency Science Advisor.[21] In addition, while approval to move draft assessments to external peer review had been made by the NCEA Director, according to EPA officials, in 2006, the Assistant Administrator started approving drafts for the first of three external reviews of IRIS assessments—the initial OMB/interagency review. However, this change occurred informally and was not reflected in the existing standard operating procedures.[22] We also note that, starting in 2004, chemical managers were required to provide a fact sheet on final IRIS assessments to the Assistant Administrator for review and approval before the assessments could be posted on the Web site.[23] Raising the level at which various approvals are made has added time to the process

[21]In January 2006, the Assistant Administrator for Research and Development was appointed as EPA's Science Advisor.

[22]EPA officials said that in July 2007, approval authority to send draft assessments to OMB was again devolved to the Director, NCEA.

[23]According to the fiscal year 2004, 2005, and 2006 standard operating procedures for IRIS assessments, before an assessment is posted on the Web site, chemical managers are required to (1) brief the IRIS Program Director and other NCEA management on any significant changes since external review and (2) prepare a fact sheet for review and approval by the Assistant Administrator, Office of Research and Development, before the IRIS Program Director submits the final assessment documents to the IRIS Web master for posting on the IRIS Web site.

because it involves additional briefings, additional revisions and negotiations over revisions, and, at times, delays due to scheduling difficulties. As a result, it is important for EPA to both articulate and evaluate its internal review process to help ensure the appropriate balance between product quality and timeliness.

Finally, in addition to process and approval clarifications, it also appears that the IRIS program could benefit from more rigorous management attention and oversight. For example, the risk assessment for chloroform—identified as one of the highest-priority assessments requested by the EPA Office of Air and Radiation—was first announced in a January 1998 *Federal Register* notice; however, the chemical manager for the chloroform assessment retired from the agency in late 2004, and a new chemical manager was not assigned to this assessment until early 2007.[24] Although EPA continued to identify this assessment as ongoing, it was actually unstaffed and therefore suspended for at least 2 years. In addition, a relatively simple, less controversial assessment of 2,2,4-trimethylpentane, which concluded that there were insufficient scientific data to either quantify the noncancer health risks associated with the chemical or to assess its potential to cause cancer, took more than 4 years to complete. EPA officials could not explain why this assessment—which should have taken less than a year to complete—took so long, aside from noting that the responsible staff had been given other high-priority assignments during this time. EPA needs to ensure that its IRIS assessments are given high priority and adequately staffed so that costly delays are avoided.

Congressional Actions

Another factor that can delay the completion of IRIS assessments is the potential for congressional involvement in assessments that become controversial, such as those with potentially significant economic effects. Because of the potential for such assessments to lead to regulatory actions that can significantly affect certain industries or federal agencies, it is particularly important that these assessments effectively and appropriately use the best available science. Even assuming the best available science,

[24]A December 1998 notice stated that EPA planned to complete the chloroform assessment, as well as 23 other assessments, in fiscal year 1999 or fiscal year 2000. In 2001, EPA completed assessments addressing oral exposure to chloroform (oral RfD and cancer assessments); however, the assessment addressing inhalation exposure (RfC) needed by the Office of Air and Radiation is currently being drafted. Since 2002, EPA has been reporting the chloroform (inhalation route) assessment as being under way or generally complete and planned for entry into IRIS within a year or 2.

however, uncertainties remain an inherent aspect of complex chemical risk assessments. As the National Academies has noted, "A risk assessment usually involves incomplete data, scientific uncertainty, and the need for expert judgment" and "almost every risk assessment is open to challenge on one ground or another."[25] As a result, the assessments may be questioned on various scientific and technical grounds and subjected to intense national scrutiny by many individuals and organizations, including the media. Constituents may contact their elected representatives with their concerns, and politicians are likely to become involved, either supporting the content of the assessments or challenging it. Because of this debate, Members of the Congress, congressional committees, or the Congress as a whole may direct EPA to take certain steps before finalizing a particular assessment. While the intense scrutiny to which some chemical assessments are subjected can result in improved assessments, all uncertainties cannot be eliminated and controversies can continue beyond the point at which additional analysis is helpful. Further, addressing questions and concerns about assessments often involves considerable rework and takes a significant amount of time. EPA strives to balance the desire for the best possible assessment with its responsibilities for protecting the public health, which it can only do with timely assessments of chemicals. That being said, it can be challenging for EPA to both identify and achieve the proper balance between these competing goals.

In the case of certain controversial chemical assessments, actions by congressional committees and individual members have led EPA to, for example, postpone completion of the IRIS assessment of formaldehyde for years until an update of an epidemiological study that had just been released was completed. Another response to congressional concerns is EPA's decision to reconsider the quantitative noncancer assessment of a chemical, dibutyl phthalate, that had completed all internal and external reviews and was ready to be released in 2007. The noncancer assessment, an update to the assessment completed in 1990, would have allowed more exposure to dibutyl phthalate than the earlier assessment. In 2000, the Department of Health and Human Services' National Toxicology Program concluded that dibutyl phthalate may adversely affect human reproduction or development if exposures are sufficiently high. This chemical,

[25]National Academies, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget Committee to Review the OMB Risk Assessment Bulletin* (2007).

regulated under the Clean Air Act's air toxics program, is used in many consumer products, such as cosmetics, nail polishes, fragrances, wood stains, and toys; the European Union has banned its use in cosmetics and restricted its use in children's toys containing concentrations of phthalates in excess of 0.1 percent. Similarly, after January 1, 2009, a California statute enacted in 2007 will prohibit the manufacture, sale, or distribution of certain toys and child care articles if the products contain concentrations of phthalates exceeding 0.1 percent.[26] Because of congressional questions and comments from the Natural Resources Defense Council about, among other things, the adequacy of the uncertainty factors used in the analysis and the lack of consideration in the draft assessment of cumulative exposure to multiple phthalates (similar chemicals in the same class) that have similar health effects, EPA has suspended the assessment. In December 2007, an EPA official said that EPA has decided to seek advice from the National Academies on whether the agency should develop a new type of assessment for this chemical—one that would assess a class of related chemicals. If EPA decides to develop a new, cumulative IRIS assessment, it will likely be many years before an updated IRIS assessment addressing dibutyl phthalate is completed.[27]

Compounding Effect of Delays

An overarching factor that affects EPA's ability to complete IRIS assessments in a timely manner is that once a delay in the assessment process occurs, work that has been completed can become outdated, necessitating rework throughout some or all of the assessment process. For example, delays often require repeating reviews of the scientific literature on a chemical to take into account the time that has passed since the literature review was completed; this, in turn, may require detailed analyses of any new studies found to be relevant. Moreover, new risk assessment guidelines and cutting-edge methodologies that the agency has started applying to other assessments may now need to be applied to an assessment being reworked to meet current assessment requirements and standards and the expectations of peer reviewers. Once these analyses are

[26]The European Union and California restrictions cover five phthalates, including dibutyl phthalate.

[27]IRIS assessments cover individual chemicals, not cumulative exposure to multiple related chemicals. This is an emerging risk assessment issue that will require developing new assessment methodologies. The congressional letter expressed concerns that the draft IRIS assessment would not adequately protect public health but did not request that it be entirely redone. Among other things, the Natural Resources Defense Council letter suggested that EPA revisit its decisions regarding the uncertainty factors used.

complete, the draft will likely need to be revised and again subjected to internal reviews, OMB/interagency reviews, and scientific peer review. In addition, the longer an assessment is in progress, the more likely it becomes that staff will change due to retirements and resignations; in turn, newly assigned chemical managers face a learning curve in reviewing often voluminous data and analyses. For example, at least four chemical managers have been assigned to the nitrobenzene assessment since it was started in 1998. Overall, even a single delay can have a domino effect—having far-reaching, time-consuming consequences, in some cases, requiring that the assessment process essentially start over. In addition, because chemical managers must continue to devote time and attention to assessments that experience delays—often repeating prior steps to update the assessments—their ability to work on other ongoing assessments and undertake new ones is limited.

Key IRIS Assessments Have Been Delayed by Some of These Factors

Some key IRIS assessments have been in progress for a number of years, in part because of delays stemming from one or more of the factors discussed above. Examples include the following:

Naphthalene. EPA started the IRIS assessment of cancer risks stemming from the inhalation of naphthalene in 2002. Naphthalene is used in jet fuel and in the production of widely used commercial products such as moth balls, dyes, insecticides, and plasticizers. According to a presentation delivered at the 2007 annual meeting of the Society for Risk Analysis by an Army Corps of Engineers toxicologist,[28] "The changing naphthalene regulatory environment includes a draft EPA risk assessment that if/when finalized, will change naphthalene's status from 'possible' to 'likely' human carcinogen."[29] Thus, according to this presentation, one potential impact of this IRIS assessment on DOD is that DOD would need to provide many

[28]Presentations at the Society for Risk Analysis meting reflect the views of the authors and "do not necessarily reflect the views of any other organization or agency."

[29]Using its 1996 Proposed Guidelines for Carcinogen Risk Assessment, EPA concluded in the 1998 IRIS assessment of naphthalene that its human carcinogenic potential could not be determined at that time, but noted that there was suggestive evidence of potential human carcinogenicity. (EPA also noted that under its 1986 cancer guidelines, EPA classified naphthalene as a possible human carcinogen.) Subsequently, in 2002, the International Agency for Research on Cancer (IARC), part of the World Health Organization, concluded that naphthalene is possibly carcinogenic to humans; in 2004, the Department of Human Health and Services' National Toxicology Program concluded that naphthalene can reasonably be anticipated to be a human carcinogen. EPA's current assessment will be subject to the agency's 2005 cancer guidelines.

employees exposed to naphthalene with equipment measuring their exposure to the chemical. In addition, because many military bases are contaminated with naphthalene, a component of jet fuel (approximately 1 percent to 3 percent) used by all DOD services, DOD could face extensive cleanup costs. By 2004, 2 years after starting the assessment, EPA had drafted a chemical assessment that had completed internal peer reviews and was about to be sent to an external peer review committee. Once it returned from external review, the next step, at that time, would have been a formal review by EPA's IRIS Agency Review Committee. If approved, the assessment would have been completed and released. However, in part because of concerns raised by DOD, OMB asked to review the assessment and conducted an interagency review of the draft. In their 2004 reviews of the draft IRIS assessment, both OMB and DOD raised a number of concerns about the assessment and suggested to EPA that it be suspended until additional research could be completed to address what they considered to be significant uncertainties associated with the assessment. Although all of the issues raised by OMB and DOD were not resolved, EPA continued with its assessment by submitting the draft for external peer review, which was completed in September 2004.[30] However, according to EPA, OMB continued to object to the draft IRIS assessment and directed EPA to convene an additional expert review panel on genotoxicity to obtain recommendations about short-term tests that OMB thought could be done quickly.[31] According to EPA, this added 6 months to the process, and the panel, which met in April 2005, concluded that the research that OMB was proposing could not be conducted in the short term. Nonetheless, EPA officials said that the second expert panel review did not eliminate OMB's concerns regarding the assessment, which they described as reaching a stalemate. In September 2006, EPA decided, however, to proceed with developing the assessment. By this time, the naphthalene assessment had been in progress for over 4 years; EPA decided that the IRIS noncancer assessment, issued in 1998, was outdated and needed to be revisited. Thus, EPA expanded the IRIS naphthalene assessment to include both noncancer and cancer assessments. As a result, 6 years after the naphthalene assessment began, it is now back at the drafting stage. The assessment now will need to reflect relevant

[30]According to DOD, EPA did not specifically ask the peer reviewers to address some of the technical questions DOD had raised and wanted the peer review to address.

[31]Genotoxic substances are a type of carcinogen, specifically those capable of causing genetic mutation and of contributing to the development of tumors. This includes both certain chemical compounds and certain types of radiation.

research completed since the draft underwent initial external peer review in 2004, and it will have to undergo all of the IRIS assessment steps again, including additional internal and external reviews that are now required. This series of delays has limited EPA's ability to conduct its mission. For example, the Office of Air and Radiation has identified the naphthalene assessment as one of its highest-priority needs for its air toxics program. In addition, the Office of Solid Waste and Emergency Response considers the naphthalene assessment a high priority for the Superfund program—naphthalene has been found in at least 654 of Superfund's current or former National Priorities List sites.[32] Although EPA currently estimates that it will complete the assessment in 2009, meeting this revised estimate will be challenging, given all of the steps that are yet to be completed and the extensive external scrutiny to which it will continue to be subjected.

Royal Demolition Explosive. This chemical, also called RDX or hexahydro-1,3,5-trinitrotriazine, is a highly powerful explosive used by the U.S. military in thousands of munitions. Currently classified by EPA as a possible human carcinogen, this chemical is known to leach from soil to groundwater. Royal Demolition Explosive can cause seizures in humans and animals when large amounts are inhaled or ingested, but the effects of long-term, low-level exposure on the nervous system are unknown. As is the case with naphthalene, the IRIS assessment could potentially require DOD to undertake a number of actions, including steps to protect its employees from the effects of this chemical and to clean up many contaminated sites. Although EPA started an IRIS assessment of Royal Demolition Explosive in 2000, it has made minimal progress on the assessment because EPA agreed to a request by DOD to wait for the results of DOD-sponsored research on this chemical. In 2007, EPA began to actively work on this assessment, although some of the DOD-sponsored research is still outstanding.

Formaldehyde. EPA began an IRIS assessment of formaldehyde in 1997 because the existing assessment was determined to be outdated.[33] Formaldehyde is a colorless, flammable, strong-smelling gas used to manufacture building materials, such as pressed wood products, and used in many household products, including paper, pharmaceuticals, and leather goods. While EPA currently classifies formaldehyde as a probable

[32]The National Priorities List is EPA's list of seriously contaminated sites.

[33]The cancer portion of the formaldehyde assessment was originally issued in 1989 and updated in 1991; the noncancer assessment was added in 1990.

human carcinogen, the International Agency for Research on Cancer (IARC), part of the World Health Organization, classifies formaldehyde as a known human carcinogen. Since 1986, studies of industrial of workers have suggested that formaldehyde exposure is associated with nasopharyngeal cancer, and possibly with leukemia. For example, in 2003 and 2004, the National Cancer Institute (NCI) and the National Institute of Occupational Safety and Health (NIOSH) released epidemiological studies following up on earlier studies tracking about 26,000 and 11,000 industrial workers, respectively, exposed to formaldehyde; the updates showed exposure to formaldehyde might also cause leukemia in humans, in addition to the cancer types previously identified. According to NCI officials, the key findings in their follow-up study were an increase in leukemia deaths and, more significantly, an exposure/response relationship between formaldehyde and leukemia—as exposure increased, the incidence of leukemia also rose. As with the earlier study, NCI found more cases of a rare form of cancer, nasopharyngeal cancer, than would usually be expected. The studies from NCI and NIOSH were published in 2003 and 2004,[34] around the time that EPA was still drafting its IRIS assessment. In November 2004, the Chairman of the Senate Environment and Public Works Committee requested that EPA delay completion of its IRIS assessment until an update to the just-released NCI study could be conducted, indicating that the effort would take, at most, 18 months. EPA agreed to wait—and more than 3 years later, the NCI update is not yet complete. As of December 2007, NCI estimates that the study will be completed in two stages, one in mid-2008 and the second one later that year. An NCI official said that the additional leukemia deaths identified in the update provide "greater power" to detect associations between exposure to formaldehyde and cancer. EPA's inability to complete the IRIS assessment it started more than 10 years ago in a timely manner has had a significant impact on EPA's air toxics program. Specifically, when EPA

[34]NCI published the results of its study in two publications. The first study, published in November 2003, focused on the association between formaldehyde exposure and leukemia. M. Hauptmann, J. H. Lubin, P. A. Stewart, R. B. Hayes, A. Blair, "Mortality from Lymphohematopoietic Malignancies among Workers in Formaldehyde Industries," *Journal of the National Cancer Institute* (2003). The second study, published in June 2004, evaluated the association between formaldehyde exposure and other cancers—including nasopharyngeal cancer. M. Hauptmann, J. H. Lubin, P. A. Stewart, R. B. Hayes, A. Blair, "Mortality from Solid Cancers among Workers in Formaldehyde Industries," *American Journal of Epidemiology* (2004). The results of the NIOSH study were described in one publication, dated March 2004, which assessed mortality from all causes and all cancers. L. E. Pinkerton, M. J. Hein, L. T. Stayner, "Mortality among a Cohort of Garment Workers Exposed to Formaldehyde: an Update," *Occupational and Environmental Medicine* (2004).

promulgated a national emissions standard for hazardous air pollutants covering facilities in the plywood and composite wood industries in 2004, EPA's Office of Air and Radiation took the unusual step of not using the existing IRIS estimate but rather decided to use a cancer risk estimate developed by an industry-funded organization, the CIIT Centers for Health Research (formerly, the Chemical Industry Institute of Toxicology) that had been used by the Canadian health protection agency. The IRIS cancer risk factor had been subject to criticism because it was last revised in 1991 and was based on data from the 1980s. In its final rule, EPA stated that "the dose-response value in IRIS is based on a 1987 study, and no longer represents the best available science in the peer-reviewed literature." The CIIT quantitative cancer risk estimate that EPA used in its health risk assessment in the plywood and composite wood national emissions standard indicates a potency about 2,400 times lower than the estimate in IRIS that was being re-evaluated and that did not yet consider the 2003 and 2004 NCI and NIOSH epidemiological studies. According to an EPA official, an IRIS cancer risk factor based on the 2003 and 2004 NCI and NIOSH studies would likely be close to the current IRIS assessment, which EPA has been attempting to update since 1997. The decision to use the CIIT assessment in the plywood national emissions standard was controversial, and officials in EPA's National Center for Environmental Assessment said the center identified numerous problems with the CIIT estimate. Nonetheless, the Office of Air and Radiation used the CIIT value, and that decision was a factor in EPA exempting certain facilities with formaldehyde emissions from the national emissions standard. In June 2007, a federal appellate court struck down the rule, holding that EPA's decision to exempt certain facilities that EPA asserted presented a low health risk exceeded the agency's authority under the Clean Air Act.[35] Further, the continued delays of the IRIS assessment of formaldehyde—currently estimated to be completed in 2010 but after almost 11 years still in the draft development stage—will impact the quality of other EPA regulatory actions, including other air toxics rules and requirements.

Trichloroethylene. Also known as TCE, this chemical is a solvent widely used as a degreasing agent in industrial and manufacturing settings; it is a common environmental contaminant in air, soil, surface water, and groundwater. TCE has been linked to cancer, including childhood cancer,

[35]*Natural Resources Defense Council v. E.P.A.*, 489 F.3d 1364, 1372-73 (D.C. Cir, 2007). The court did not specifically address EPA's reliance on the CIIT study, holding instead that the Clean Air Act prohibited establishment of the exemptions at issue.

and other significant health hazards, such as birth defects. TCE is the most frequently reported organic contaminant in groundwater, and contaminated drinking water has been found at Camp Lejeune, a large Marine Corps base in North Carolina. TCE has also been found at Superfund sites and at many industrial and government facilities, including aircraft and spacecraft manufacturing operations. In 1995, the International Agency for Research on Cancer classified TCE as a probable human carcinogen, and in 2000, the Department of Health and Human Services' National Toxicology Program concluded that it is reasonably anticipated to be a human carcinogen. Because of questions raised by peer reviewers about the IRIS cancer assessment for TCE, EPA withdrew it from IRIS in 1989 but did not initiate a new TCE cancer assessment until 1998. In 2001, EPA issued a draft IRIS assessment for TCE that proposed a range of toxicity values indicating a higher potency than in the prior IRIS values and characterizing TCE as "highly likely to produce cancer in humans." The draft assessment, which became controversial, was peer reviewed by EPA's Scientific Advisory Board and released for public comment. A number of scientific issues were raised during the course of these reviews, including how EPA had applied emerging risk assessment methods—such as assessing cumulative effects (of TCE and its metabolites) and using a physiologically based pharmacokinetic model—and the uncertainty associated with the new methods themselves.[36] To help address these issues, EPA, DOD, DOE, and NASA sponsored a National Academies review to provide guidance. The National Academies report, which was issued in 2006, concluded that the weight of evidence of cancer and other health risks from TCE exposure had strengthened since 2001 and recommended that the risk assessment be finalized with currently available data so that risk management decisions could be made expeditiously. The report specifically noted that while some additional information would allow for more precise estimates of risk, this information was not necessary for developing a credible risk assessment. Nonetheless, 10 years after EPA started its IRIS assessment, the TCE assessment is back at the draft development stage. EPA estimates this assessment will be finalized in 2010. More in line with the National Academies' recommendation to act expeditiously, five senators introduced a bill in August 2007 that, among other things, would require EPA to both

[36]Physiologically based pharmacokinetic models are a class of dosimetry models that are useful for predicting internal doses to target organs. With the appropriate data, these models can be used to extrapolate across species and exposure scenarios and address various sources of uncertainty in risk assessments.

establish IRIS values for TCE and issue final drinking water standards for this contaminant within 18 months.

Tetrachloroethylene. EPA started an IRIS assessment of tetrachloroethylene—also called perchloroethylene or "perc"—in 1998. Tetrachloroethylene is a manufactured chemical widely used for dry cleaning of fabrics, metal degreasing, and making some consumer products and other chemicals. Tetrachloroethylene is a widespread groundwater contaminant, and the Department of Health and Human Services' National Toxicology Program has determined that it is reasonably anticipated to be a carcinogen. The IRIS database currently contains a 1988 noncancer assessment based on oral exposure that will be updated in the ongoing assessment. Importantly, the ongoing assessment will also provide a noncancer inhalation risk and a cancer assessment. The IRIS agency review of the draft assessment was completed in February 2005, the draft assessment was sent to OMB for OMB/interagency review in September 2005, and the OMB/interagency review was completed in March 2006. EPA had determined to have the next step, external peer review, conducted by the National Academies—the peer review choice reserved for chemical assessments that are particularly significant or controversial. EPA contracted with the National Academies for a review by an expert panel, and the review was scheduled to start in June 2006 and be completed in 15 months. However, as of December 2007, the draft assessment has not yet been provided to the National Academies. After verbally agreeing with both the noncancer and cancer assessments following briefings on the assessments, the Assistant Administrator, Office of Research and Development, subsequently requested that additional uncertainty analyses—including some quantitative analyses—be conducted and included in the assessment before the draft was released to the National Academies for peer review. As discussed above, quantitative uncertainty analysis is a risk assessment tool that is currently being developed, and although the agency is working on developing policies and procedures for uncertainty analysis, such guidance currently does not exist. The draft tetrachloroethylene assessment has been delayed since early 2006 as EPA staff have gone back and forth with the Assistant Administrator trying to reach agreement on key issues such as whether a linear or nonlinear model is most appropriate for the cancer assessment and how uncertainty should be qualitatively and quantitatively characterized. EPA officials and staff noted that some of the most experienced staff are being used for these efforts, limiting their ability to work on other IRIS assessments. In addition, the significant delay has impacted the planned National Academies peer review because the current contract, which has already been extended once, cannot be

extended beyond December 2008. The peer review was initially estimated to take 15 months. As a result, a new contract and the appointment of another panel may be required.

Dioxin. The dioxin assessment is an example of an IRIS assessment that has been, and will likely continue to be, a political as well as a scientific issue. Often the byproducts of combustion and other industrial processes, complex mixtures of dioxins enter the food chain and human diet through emissions into the air that settle on soil, plants, and water. EPA's initial dioxin assessment, published in 1985, focused on the dioxin TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin) because animal studies in the 1970s showed it to be the most potent cancer-causing chemical studied to date. Several years later, EPA decided to conduct a reassessment of dioxin because of major advances that had occurred in the scientific understanding of dioxin toxicity and significant new studies on dioxins' potential adverse health effects. Initially started in 1991, this assessment has involved repeated literature searches and peer reviews. For example, a draft of the updated assessment was reviewed by a scientific peer review panel in 1995, and three panels reviewed key segments of later versions of the draft in 1997 and 2000. In 2002, EPA officials said that the assessment would conclude that dioxin may adversely affect human health at lower exposure levels than had previously been thought and that most exposure to dioxins occurs from eating such American dietary staples as meats, fish, and dairy products, which contain minute traces of dioxins. These foods contain dioxins because animals eat plants and commercial feed and drink water contaminated with dioxins, which then accumulate in animals' fatty tissue. It is clear that EPA's dioxin risk assessment could have a potentially significant impact on consumers and on the food and agriculture industries. As EPA moved closer to finalizing the assessment, in 2003 the agency was directed in a congressional appropriations conference committee report to not issue the assessment until it had been reviewed by the National Academies. The National Academies provided EPA with a report in July 2006. In developing a response to the report, which the agency is currently doing, EPA must include new studies and risk assessment approaches that did not exist when the assessment was drafted. EPA officials said the assessment will be subject to the IRIS review process once its response to the National Academies' report is drafted. As of 2008, EPA has been developing the dioxin assessment, which has potentially significant health implications for all Americans, for 17 years.

While Appropriate Coordination with Federal Agencies Could Help EPA Resolve IRIS Assessment Controversies More Efficiently, EPA's Proposed Expansion of Agencies' Roles in IRIS Assessments Would Cause Further Delays and Limit Their Credibility

Although an interagency review process managed by OMB was informally incorporated into the IRIS assessment starting in 2004, federal agencies continue to believe they should have greater and more formal roles in EPA's development of IRIS assessments given the potential impact of the assessments on either their missions or their budgets, such as the need to redesign systems to eliminate hazardous materials or to clean up contaminated sites. These agencies—including DOD, DOE, the Department of Homeland Security, the Department of Transportation, and NASA—have sought earlier, more formal involvement in IRIS assessments than is currently provided through the OMB/interagency review process and the other avenues for input that currently exist, which include nominating chemicals for assessment and providing relevant studies for planned or ongoing assessments. Officials from DOD, NASA, and DOE told us there is a lack of formality and transparency about how they can provide input and when it is appropriate to do so. For example, they seek a more formal process for nominating chemicals and providing relevant studies for planned or ongoing assessments, and they want to help decide questions for the peer reviews of IRIS assessments. They said that reducing the scientific uncertainty in IRIS assessments is important because some assessments can have significant impacts on their operations and budgets. Also, the officials said that their involvement with IRIS assessments occurs too late in the process, leading to disagreement among EPA and the agencies after the assessments are drafted, and unnecessarily delaying certain assessments, such as naphthalene, TCE, and dioxin.

Along these lines, we concluded in a 2006 report that EPA could help ensure consistent, transparent, and high-quality risk assessments by working with stakeholders early and periodically throughout the process to identify, among other things, key issues and studies that need to be considered in the analysis.[37] Nonetheless, we believe that if EPA is to increase the involvement of DOD and other potentially affected federal agencies in the IRIS assessment process, it is important to do so in a way that enables EPA to balance the benefits of increased interagency coordination with EPA's need to improve the timeliness of its IRIS assessments and to ensure their credibility with proper controls.

[37]GAO, *Human Health Risk Assessment: EPA Has Taken Steps to Strengthen Its Process, but Improvements Needed in Planning, Data Development, and Training*, GAO-06-595 (Washington, D.C.: May 31, 2006).

In response to the continuing concerns of some federal agencies regarding the IRIS assessment process, EPA has, for several years, been working to develop a formal IRIS assessment process that would give other federal agencies a more significant role in the process.[38] EPA consulted with an Interagency Work Group on the IRIS Process, which includes officials representing potentially affected agencies such as DOD, DOE, and NASA, as well as officials from other agencies that develop health assessments of chemicals, such as the Department of Health and Human Services' ATSDR. OMB, the Department of Homeland Security, and the White House Office of Science and Technology Policy are also represented on the working group.

EPA developed a draft process in early 2007 that the agency believed would be acceptable to the interagency work group. One of the key aspects of EPA's draft process is an increased role for other agencies—including those whose operations and resource levels could be affected by the results of the assessments—in providing input to IRIS chemical assessments. Specifically, federal agencies would have the opportunity to be involved, or provide some form of input, at almost every step of EPA's IRIS assessment process. Most significantly, the draft proposed process would provide federal agencies with several opportunities during the IRIS assessment process to identify chemicals of interest to them as "mission critical." As defined in the draft process, a mission-critical chemical is one that is "an integral component to the successful and safe conduct of an agency's mission in any or all phases of operations." Potential impacts on the use of mission-critical chemicals assessed under the IRIS program include "cessation or degradation of the conduct of the mission and/or unacceptable resource constraints."[39] A mission-critical designation would add requirements to the assessment process, providing other federal agencies with increased involvement in IRIS assessment decisions. As outlined, this designation could add 2 or more years to the process (see shaded boxes in fig. 5 for these additional requirements).

[38]Developing this process, publishing a notice about it in the *Federal Register*, and holding a public meeting to obtain public input on the proposed process has been an item OMB has included in its PART review of EPA's human health risk assessment program.

[39]Under the proposal, EPA could also identify chemicals "of major importance" which would be treated as mission-critical chemicals.

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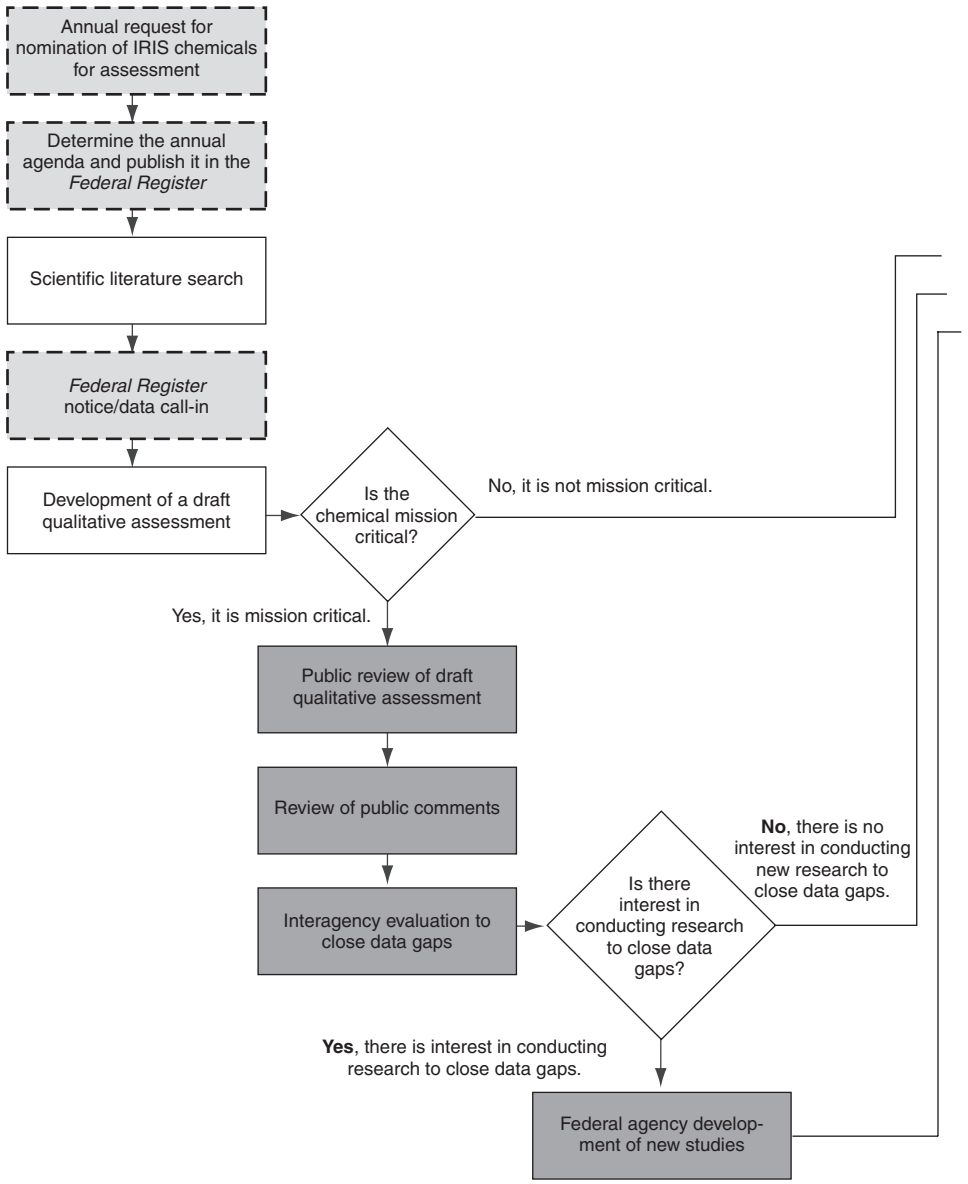
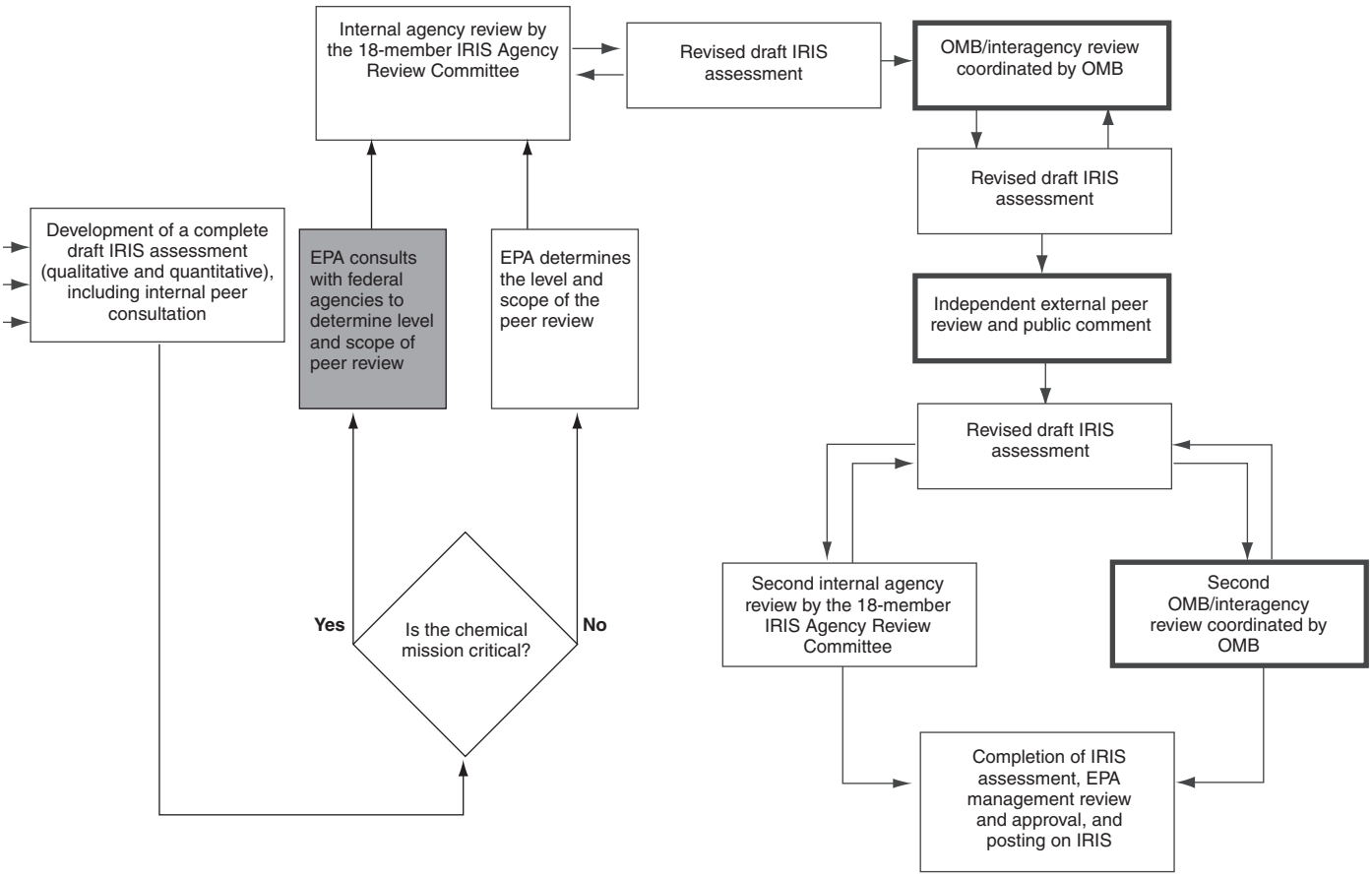
Figure 5: EPA's Draft Proposed IRIS Assessment Process





Darker shaded boxes are additional steps, under EPA's planned changes, to its assessment process and indicate steps where EPA has provided additional opportunity for input from potentially affected federal agencies for mission-critical chemicals.

Lighter shaded boxes with dotted lines indicate steps where EPA has provided additional opportunity for input from potentially affected federal agencies for all chemicals.

White boxes with heavy lines indicate steps where potentially affected federal agencies already had an opportunity for input.

Source: GAO analysis of EPA information.

The additional requirements for assessments of mission-critical chemicals that would lengthen the IRIS assessment process include the following:

- *The opportunity for federal agencies and the public to identify any additional information that is available on a chemical and to correct any errors on EPA's new first assessment draft—a draft qualitative assessment.*[40] EPA estimates that the public comment period alone would add 45 days to the assessment process.

- *An opportunity for potentially affected federal agencies to review public comments made during the error correction step and initiate a meeting with EPA if they want to discuss a particular set of comments.* EPA estimates that this step, which includes EPA's review and analysis of the public comments, would add 30 days to the process.

- *An opportunity for potentially affected federal agencies to fill a data gap or eliminate an uncertainty factor that is identified in the qualitative draft.* If an agency believes it can sponsor research to fill a significant data gap, EPA would then suspend the assessment process for up to 18 months to allow that agency time to conduct research and have the completed study peer reviewed.

In addition, the draft proposed process would give other federal agencies a formal role in helping EPA determine the level of independent peer review assessments for mission-critical chemicals—that is, whether the peer reviews would be conducted by EPA Science Advisory Board panels, National Academies' panels, or panels organized by an EPA contractor. In addition, the other federal agencies would be able to help determine the panel members' areas of scientific expertise as well as the scope of the peer reviews and the specific issues they would address.

Finally, the draft proposed process would also formalize the roles of other federal agencies in nominating chemicals for assessment, helping EPA determine the chemicals it would assess, and providing scientific information (reports, studies, etc.) for the assessments EPA undertakes. In the past, EPA sought such information in public notices in the *Federal Register*, and federal agencies could have provided their input either in

[40]Under EPA's draft proposed IRIS assessment process, EPA would develop, for all chemicals, an additional draft IRIS assessment—one that includes only qualitative information—that must undergo internal review. Only draft qualitative assessments for chemicals that are identified as mission critical would be released for the error correction step.

response to these notices or by contacting EPA officials directly. However, in response to criticisms that EPA's approach to seeking input from the public was not appropriate for other federal agencies, under the proposed process, EPA would directly reach out to other federal agencies for this input by separately communicating these requests to them at the time it publishes its notices in the *Federal Register*. The draft proposed IRIS process would also formalize the OMB/interagency reviews, which provide other federal agencies with the opportunity to provide comments on IRIS draft assessments both before and after the draft assessments are provided to external peer reviewers. The OMB/interagency reviews would continue to be managed by OMB.

EPA has acknowledged that the additional steps and opportunities for input from other federal agencies that its draft proposed process would provide will add more time to an already lengthy process. Specifically, under the proposed process we reviewed, EPA officials estimated that IRIS assessments for standard chemicals would take roughly 2-1/2 years to complete and that an additional 2 to 3 years would be needed for mission-critical chemicals. In February 2008, the Assistant Administrator, Office of Research and Development, updated these time frames, estimating that most assessments would take between 3 and 4-1/2 years to complete, while assessments of mission-critical chemicals would take up to 6 years. However, these estimates appear to be optimistic considering the length of time ongoing assessments—which have not been subject to additional process steps—have been in progress: most for more than 5 years and many for more than 9 years. Further, when assessments take longer than 2 years, they can become subject to substantial delays stemming from the need to redo key analyses to take into account changing science and assessment methodologies.

According to officials from EPA and some of the potentially affected federal agencies, the key goals of the draft proposed changes to the IRIS assessment process are to (1) fill data gaps to reduce uncertainty in the IRIS assessments and (2) prevent disagreements among EPA and other federal agencies about assessments late in the IRIS assessment process. As discussed earlier, disagreements have arisen late in the process in the past and have significantly delayed the completion of some assessments. These goals are important, and it is appropriate for EPA and the federal agencies to find ways to achieve them. However, some of the proposed changes would result in assessments being caught in a continuous cycle of updates and revisions—delaying the completion of assessments of chemicals with potentially significant health impacts for many years. As discussed above, delays for any reason—including waiting for new

research to fill data gaps—can have a compounding effect on time frames because delays often require extensive rework, such as updates to reflect other studies that have come out in the interim, performing additional analyses to reflect the current state of the science of risk assessment tools, and other rounds of interagency or external peer reviews because of changes in the assessments. Thus, changing from a reliance on the best available scientific data at the time an assessment is conducted to a reliance on research that has either not yet started or been completed in order to fill scientific data gaps is a decision that can have a significant impact on assessment completion dates.

Further, although EPA has said that IRIS assessments would only be suspended to wait for shorter-term studies, such as those assessing modes of action, we and several agency officials we spoke with believe that the time needed to plan, conduct, and complete research that would address significant data gaps, and have it peer reviewed, would likely take longer than the 18 months EPA would allow under its draft proposed IRIS process. In addition, although the draft process would set a limit on the time the assessments can be suspended to await studies, the enforcement of such time frames could prove to be difficult when research schedules slip. And not waiting for study results beyond the 18-month limit could, in fact, undo all of the efforts expended to avoid disagreements in the later stages of the assessments. Also, EPA's prior experience with waiting for studies, such as in the case of the formaldehyde assessment discussed earlier, shows that estimates of completion dates for these studies can stretch out from months to years. Finally, the extent to which new research would provide information that would actually reduce key scientific uncertainties in the IRIS assessments is not known until the research is completed and peer reviewed.

In discussing with us the need for additional time to conduct new research to fill scientific data gaps for chemicals defined as mission critical, DOD officials emphasized that the federal agencies believe it is important that scientific uncertainties are reduced to the maximum extent practical within a reasonable time frame before IRIS assessments of mission-critical chemicals with high uncertainty are completed. The potential impacts of IRIS assessments on DOD—should risk assessments using the IRIS data lead to regulatory actions—could include the need to (1) conduct research and development of material substitutes; (2) redesign systems and processes to eliminate hazardous materials; (3) conduct research and development of treatment or cleanup technologies; (4) improve personal protective clothing, equipment, and procedures; and (5) provide for special handling and storage of chemicals.

However, the reality is that scientific data gaps will almost always exist. EPA, whose mission includes protecting the public and the environment from harmful chemicals, must decide whether to use assumptions and estimates to address data gaps or to wait for research that could potentially fill some of the data gaps. On this issue, in discussing the fact that EPA must address many environmental risks with incomplete data and a lack of consensus about assumptions, the agency has stated that it seeks to strike a balance among fairness, accuracy, and efficient action because not acting until data quality improves can result in substantial harm to human health, safety, and the environment. Along these lines, as discussed earlier, a National Academies panel recently reported on a chemical of interest (trichloroethylene) to several federal agencies that would likely be defined as mission critical under the proposed IRIS process. The National Academies' report recommended that the risk assessment be finalized with currently available data, rather than waiting for additional information to address scientific uncertainties, so that risk management decisions can be made expeditiously because the evidence on risks to human health have strengthened. The National Academies specifically noted that while some additional information would allow for more precise estimates of risk, this information is not necessary at this time for developing a credible risk assessment. EPA started the assessment in 1998, and it has been subject to multiple independent peer reviews. However, EPA is currently preparing another assessment draft that will need to undergo the IRIS assessment process a second time. As such, the draft will be to subject to the OMB/interagency reviews and another independent peer review before it can be finalized. We note that if EPA's proposed IRIS process is implemented, DOD and other federal agencies could designate trichloroethylene as a mission-critical chemical and have the assessment suspended for 18 months for research aimed at reducing scientific uncertainties.

EPA could potentially minimize or eliminate requests to suspend ongoing assessments to fill in scientific data gaps by better coordinating with DOD's emerging contaminants program—established in 2006—that leads and supports the Materials of Emerging Regulatory Interest Team (MERIT).[41] The intent of the emerging contaminants program is to help DOD proactively manage chemicals DOD uses or has used in its

[41]According to DOD, the Materials of Emerging Regulatory Interest Team is a virtual interagency team composed of individuals throughout DOD with a common interest in emerging contaminants.

operations that (1) are a perceived or real threat to human health or the environment and (2) lack a published health standard and/or have new information available about their sources or effects. The program seeks to identify chemicals of importance to DOD's mission that are on the regulatory horizon so that the agency can begin to make changes or identify areas of research that may minimize the impact that regulations of a particular chemical would have on the agency and its mission.

Of particular relevance to the IRIS program is the scanning component of the emerging contaminants program, which consists of a regular review of the scientific literature, periodicals, and regulatory communications for chemicals that have, or are likely to have, changing human health values or regulatory standards. DOD then further screens those chemicals that are, were, or will be used by DOD to determine whether a potential impact to DOD's mission exists. After screening, DOD conducts impact assessments to determine the severity of risk to DOD functional areas, which include environment, safety, and health protection; research and development; production, operation and maintenance, and disposal; training and readiness; and cleanup. Through these efforts, DOD seeks to identify cost-effective opportunities to proactively manage future unacceptable risks. One research area the emerging contaminants program has identified as a potentially good investment is DOD-funded health effects research aimed at filling important data gaps for mission-critical chemicals with high uncertainty factors.[42]

DOD's ongoing actions in monitoring scientific literature and identifying research that could reduce scientific uncertainties could be more effectively put to use. Specifically, enhanced coordination and collaboration between EPA and DOD's emerging contaminants program have the potential to proactively reduce some scientific uncertainties associated with chemicals that EPA is not yet assessing—as opposed to the current reactive focus on ongoing IRIS assessments. That is, under the draft proposed IRIS process changes we reviewed, DOD and other federal agencies would be able to designate ongoing chemicals as mission critical at several stages in the assessment process—and have their assessments suspended for up to 18 months to address data gaps. However, enhanced coordination and collaboration between DOD and EPA could change this essentially reactive approach to a model that is more proactive and

[42]Other possible types of DOD risk management investments include material and process substitutions and personal protective equipment.

effective. If, for example, EPA provided 2 years' notice of its intent to assess specific chemicals, rather than simply announcing the list of chemical assessments it plans to initiate during a given fiscal year, DOD and other agencies could use this time to sponsor and complete the studies they deem necessary, rather than waiting to initiate them after an IRIS assessment had started. Giving agencies 2 years' notice (which would provide them with more than 18 months to conduct additional research) would be more effective and efficient than delaying ongoing IRIS assessments for 18 months to await research, given the compounding effect of delays on IRIS assessments. We note that, to date, the emerging contaminants action list—the list of chemicals that DOD has assessed and judged to have a significant potential impact on people or the DOD mission—has focused largely on chemicals that EPA's IRIS program is already assessing. However, with some adjustments in the emerging contaminants program's focus or scope, DOD could widen its scope and help EPA with its planning process by earlier identification of the mission-critical chemicals of concern to DOD for which IRIS assessments are needed. Finally, when the emerging contaminants program identifies health research needs for chemicals considered mission critical, DOD could meet its research needs more effectively and quickly by sponsoring research as needs are identified, rather than waiting until IRIS assessments are started.

Lastly, we note that while increased coordination with potentially affected federal agencies on IRIS assessments could enhance the assessments and facilitate their completion, giving potentially affected federal agencies formal roles in some IRIS assessment decisions reduces the credibility of the assessments if proper controls, such as ensuring transparency, are not in place. While we recommended in our 2006 report on human health risk assessment that EPA consistently involve stakeholders as appropriate to the risk assessment, we made this recommendation in the context of improving the overall quality, consistency, and transparency of risk assessments. However, one aspect of EPA's draft proposed IRIS process that has proven to be controversial involves transparency. Specifically, EPA's early 2007 draft proposal included making the comments from OMB and other federal agencies provided during the OMB/interagency review process part of the public record; according to EPA, this requirement has been removed from the latest draft proposal because of concerns raised by OMB. These concerns have delayed the implementation of the planned process changes, and as of December 2007, EPA was planning to send a revised draft back to the interagency work group for review and approval.

According to DOD officials, OMB did not support certain aspects of the draft process EPA presented to the Interagency Work Group on the IRIS Process in early 2007, expressing concerns about how the proposal would address the concerns of states, industry, and environmental entities and the requirement to have agencies' comments part of the public record. The latter concern stemmed from the precedent it might set and because OMB believes that doing so would erode the effectiveness of the deliberative process among EPA and the agencies. However, because the agencies' comments on IRIS assessments are to be scientific in nature, it is unclear why agencies might not candidly comment on an IRIS assessment even if their comments would become part of the public record. In fact, officials from DOD, DOE, and NASA told us they did not object to EPA's plan to make interagency comments part of the public record because they would be scientific in nature and not part of a policy discussion.

While OMB officials would not comment directly on this issue as it relates to objections they might have to EPA's draft proposed process, one official told us that generally OMB believes that effective deliberations among federal agencies are important and that if agencies' deliberative comments are part of the public record, agency officials will not be as frank and candid as they would be under the protection of confidentiality.

However, transparency in the IRIS assessment process can provide assurance that these scientific assessments are appropriately based on the best available science and that they are not impacted by policy issues and considerations. Under the National Academies' risk assessment and risk management paradigm, policy considerations are relevant in the risk management phase, which occurs after the risk assessment phase that encompasses IRIS assessments.[43] Some of the federal agencies that would be given formal roles in some IRIS assessment decisions are particularly interested in risk management issues as they would likely face adverse consequences, such as increased cleanup costs and other legal liabilities, if EPA issues an IRIS assessment for a given chemical that results in a risk

[43]The National Academies recently addressed this issue as follows: "The committee believes that risk assessors and risk managers should talk with each other; that is, a 'conceptual distinction' does not mean establishing a wall between risk assessors and risk managers. Indeed they should have constant interaction. However, the dialogue should not bias or otherwise color the risk assessment conducted, and the activities should remain distinct; that is, risk assessors should not be performing risk management activities." National Academies, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget Committee to Review the OMB Risk Assessment Bulletin* (2007).

management decision to regulate the chemical to protect the public.[44] Consequently, to ensure credibility of the IRIS assessments, the input of these agencies into the assessment process should be transparent.

Further, when EPA and other agencies propose regulations or other actions on the basis of health risk assessments, the proposals represent policy choices. Through the rule-making process and other interagency working groups, federal agencies have the opportunity to participate in policy dialogues. Such discussions can appropriately address risk management concerns that, by definition, involve integrating risk characterization information (based, in part, on information in IRIS) with other information[45] to decide how to protect public health. In contrast, the input of federal agencies into the IRIS assessments, part of the risk assessment process, should be based solely on science issues, not policy concerns.

Conclusions

The IRIS database, one of the most significant tools that EPA has developed to effectively support its efforts to protect people and the environment from harmful chemical exposures, is at serious risk of becoming obsolete because the agency has not been able to keep its existing assessments current or complete assessments of the most important chemicals of concern. Although EPA has taken important steps to improve the IRIS program and productivity since 2000 and has developed a number of draft assessments for external review, its efforts to finalize the assessments have been thwarted by a combination of factors: the imposition of external requirements, the growing complexity and scope of risk assessments, and certain EPA management decisions. Each of these factors has led to delays in the completion of individual IRIS assessments. In addition, an overarching factor—the compounding effect of delays—has had a particularly profound impact on productivity: Even a single delay can create a cascading series of delays with far-reaching, time-consuming consequences. In fact, in some cases, it is necessary to

[44]The National Academies recently emphasized that "stakeholders from all points on the spectrum of interested parties—other state and federal agencies, advocacy groups from industry, and affected communities—can be expected to offer perspectives on the risk assessment policies under discussion." National Academies, *Scientific Review of the Proposed Risk Assessment Bulletin*.

[45]"Other information" includes economic information on the costs and benefits of mitigating the risk, technological information on the feasibility of managing the risk, and the concerns of various stakeholders.

essentially start the assessment process over because of the need to incorporate science and methodologies that have evolved since the assessments began. To effectively meet its diverse user needs, EPA must both keep the IRIS database up to date and undertake assessments of potentially dangerous chemicals not yet evaluated. Achieving these objectives will require EPA to complete IRIS assessments in a timely fashion that minimizes rework—an outcome that cannot occur unless EPA's IRIS assessment process is streamlined to routinely support timely completion of assessments. When assessments take longer than two years, they can become subject to substantial delays stemming from the need to redo key analyses to take into account changing science and assessment methodologies.

However, the manner in which other federal agencies are involved in the IRIS assessment process prevents EPA from effectively streamlining and managing its assessments. Under the current process, EPA is required to send draft assessments to OMB at two key points in the assessment process. Although the OMB/interagency reviews have no time frames or deadlines, EPA is not allowed to proceed with the assessment process until OMB agrees that EPA has sufficiently responded to agencies' comments; and OMB has also directed EPA to terminate five assessments. Further, OMB's view that disagreements between EPA and other agencies should simply be elevated to senior EPA executives for resolution is inefficient and causes delays. That is, an effective IRIS assessment process would not require the constant intervention of top-level executives, whose time is already at a premium. Moreover, the current process elevates the goal of reaching interagency agreement above achievement of IRIS program objectives and, in doing so, fails to adequately acknowledge the expertise of EPA scientists and the many other scientific experts who have prepared and reviewed the assessments. We believe that interagency coordination can enhance the quality of EPA's IRIS assessments. However, this goal would more likely be achieved if the input from other federal agencies was obtained in a manner that better ensured that EPA's scientific analyses were given appropriate weight and that provided time frames to avoid indefinite delays. Because an integral part of EPA's mission is to assess the risks associated with exposures to chemicals, the agency is best situated to establish how—and at what level—to best resolve IRIS assessment issues raised by other federal agencies. Until EPA can establish time frames for various assessment steps—including the OMB/interagency review process—and determine (1) how it will resolve interagency conflicts, (2) when assessments are ready for either independent peer review or completion, and (3) the scope of the assessments needed to support EPA programs, EPA will continue to be

hampered in its ability to develop timely and credible IRIS assessments that meet its needs and protect the environment.

Importantly, the lack of transparency of the OMB/interagency review process reduces the credibility of EPA's IRIS assessments. Because the agencies' comments and the changes EPA makes in response are treated as internal executive branch documents not subject to release outside the executive branch, the OMB/interagency reviews occur in what amounts to a black box. Specifically, the first assessment drafts that become publicly available—those provided to independent peer reviews—incorporate changes from federal agencies that may be affected by the assessments without identifying or providing reasons for the changes. Moreover, the changes EPA is proposing to its current assessment process would provide potentially affected federal agencies with a formalized opportunity to provide input at almost every step in the assessment process without addressing the extent to which agencies' input would be made part of the public record. Given the importance and sensitivity of IRIS assessments, it is critical that input from all parties, particularly agencies that may be affected by the outcome, be publicly available to alleviate concerns of potential bias in the assessments.

In addition, EPA's draft proposed changes to its IRIS assessment process—which would further expand the role of other federal agencies in the process, including the option to suspend assessments of key chemicals for up to 18 months to develop new studies—would add to the already unacceptable level of delays in completing IRIS assessments. Under its draft proposed changes, EPA estimates that assessments of certain key chemicals may take up to 6 years. Assessments of this duration are problematic—they tend to get caught in a perpetual cycle of updates and revisions. Further, we believe EPA's time estimate for assessments under its draft proposal are optimistic, as most IRIS assessments currently in progress have already been in the works for more than 5 years, including 12 that have been in progress for more than 9 years. Yet these assessments have not been subject to the additional steps and requirements under the draft proposed process.

An alternative, more efficient approach to suspending assessments while waiting for new research would be for EPA to give agencies and the public more advance notice of planned assessments, thereby providing external parties with an interest in conducting additional research on a given chemical the ability to complete their work prior to the start of the IRIS assessment. This is important because effectively maintaining the IRIS database depends on strict adherence to time frames using the best

available science. In addition, we note that OMB has raised questions about whether the proposed process sufficiently addresses the needs of private entities. Along these lines, we believe that if EPA grants special rights to other federal agencies to suspend IRIS assessments to conduct new research, it is likely that the agency would face pressure to do so for numerous other entities, including industries and individual companies that could be impacted by IRIS assessments should the assessments lead to regulatory actions.

Further, while we believe it is appropriate for EPA to identify key uncertainties in IRIS assessments and to continue to work on developing methodologies for conducting more sophisticated and meaningful uncertainty analyses, continuing to delay IRIS assessments in order to develop and test enhanced methodologies and strategies for communicating them can conflict with EPA's stated goal of seeking balance among fairness, accuracy, and efficient action. More specifically, EPA has acknowledged that not acting until data quality improves can result in substantial harm to human health, safety, and the environment. Also, as EPA continues to incorporate uncertainty analysis in its assessments, ensuring that the information is clear and useful to decision makers is important. Along these lines, the National Academies and others have warned that producing "ranges of meaningless and confusing risk estimates" could result in assessments of reduced, rather than enhanced, quality and objectivity.

Lastly, while it is difficult to overstate the importance of the IRIS program to EPA's ability to effectively conduct its mission of protecting human health and the environment, this program currently uses about 0.1 percent of EPA's annual appropriations—specifically, in fiscal year 2007, the program received about $9.6 million of EPA's $7.3 billion budget. EPA's current estimate that it will be able to complete 16 assessments a year by 2011 would represent a substantial increase over recent productivity; however, it is not clear that this level will be sufficient to maintain the viability of the IRIS database.

Recommendations for Executive Action

To develop timely chemical risk information that EPA needs to effectively conduct its mission, we are recommending that the Administrator, EPA, require the Office of Research and Development to re-evaluate its draft proposed changes to the IRIS assessment process in light of the issues raised in this report and ensure that any revised process

- clearly defines and documents a streamlined IRIS assessment process that can be conducted within time frames that minimize the need for wasteful rework and carefully considers the trade-off between the benefits of changes that involve additional steps and time—including the development of enhanced uncertainty analyses and other emerging assessment methods—and the impacts of these changes on EPA's ability to complete timely chemical assessments;

- establishes a policy that endorses conducting IRIS assessments on the basis of peer-reviewed scientific studies available at the time of the assessment and develops criteria for allowing assessments to be suspended to await the completion of scientific studies only under exceptional circumstances;

- establishes IRIS assessment needs to provide at least 2 years' notice of assessments that are planned, including criteria for making exceptions to the advance notifications, if needed;

- sets time limits for all parties, including OMB and other federal agencies, to provide comments to EPA on draft IRIS assessments; and

- periodically assesses the level of resources that should be dedicated to this significant program to meet user needs and maintain a viable IRIS database.

In addition, we recommend that the EPA Administrator take steps to better ensure that EPA has the ability to develop transparent, credible IRIS chemical assessments—an ability that relies in large part on EPA's independence in conducting these important assessments. Actions that are key to this ability include ensuring that EPA

- can determine the types of IRIS assessments to conduct on the basis of the needs of EPA's program offices and other users;

- can define the appropriate role of external federal agencies in EPA's IRIS assessment process and manage an interagency review process in a manner that enhances the quality, transparency, timeliness, and credibility of IRIS assessments, including determining when interagency issues have been appropriately addressed; and

- has the ability to provide comments by OMB and other federal agencies on draft IRIS assessments to decision makers, the Congress, and the public.

Agency Comments and Our Evaluation

In commenting on a draft of this report, EPA's Assistant Administrator for Research and Development agreed to consider our recommendations in revising the IRIS assessment process. However, EPA stated that it believed the productivity and transparency issues discussed in the draft report were misrepresented in the title and body of the report. We disagree and believe we have fairly represented IRIS productivity and transparency issues related to the IRIS assessment process. We did clarify that the transparency issues highlighted in our report focus on the IRIS assessment process rather than on the content of IRIS assessments, and we revised the report title. In addition, EPA emphasized that the proposed changes to the IRIS assessment process are still subject to change. Along these lines, we made our recommendations with the intent that they would be integrated into any revised process. In its response, EPA also estimated that under the new process, most assessments would take between 3 and 4-1/2 years; mission-critical assessments would take up to 6 years. These estimates differ from the time frames EPA officials provided during our review, and we have revised the report to reflect this. However, we believe an IRIS assessment process built around such time frames is problematic. As we state in our draft and final reports, when assessments take longer than 2 years, they can become subject to substantial delays stemming from the need to redo key analyses to take into account changing science and assessment methodologies. Finally, EPA asserted that the new process will lead to increased productivity. We disagree and have concluded that the proposed revisions would add to the already unacceptable level of delays in completing IRIS assessments.

In its comments, OMB did not specifically address the recommendations we made to EPA but disagreed with some aspects of the report, primarily regarding our characterization of the OMB-managed interagency reviews and their effects on IRIS assessments. For example, OMB indicated that it disagreed with our conclusions that the OMB/interagency reviews make it more difficult for EPA to complete IRIS assessments in a timely manner, that these reviews affect the credibility of the assessments, and that interagency comments should be transparent. We disagree with OMB and believe that we have fairly represented the OMB/interagency review process as well as the importance of input from all parties being publicly available. Given the importance and sensitivity of IRIS assessments, it is critical that input from all parties, particularly agencies that may be affected by the outcome, be publicly available to alleviate concerns of potential bias in the assessments. EPA's and OMB's comments and our detailed responses appear in appendix IV and appendix V.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of this report until 30 days from the report date. At that time, we will send copies to the Administrator, EPA; the Director, OMB; and appropriate congressional committees and other interested parties. We will also make copies available to others on request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VI.

Sincerely yours,

John B. Stephenson
Director, Natural Resources
and Environment

Appendix I: Objectives, Scope, and Methodology

This appendix details the methods we used to assess the Environmental Protection Agency's (EPA) management of its Integrated Risk Information System (IRIS). For this review, we determined (1) the outcome of steps that EPA has taken to ensure that IRIS contains current, credible chemical risk information, to address the backlog of IRIS assessments, and to respond to new requirements from the Office of Management and Budget (OMB); and (2) the potential effects of EPA's planned changes to the IRIS assessment process on EPA's ability to ensure that IRIS provides current, credible risk information.

To address these two objectives, we reviewed relevant EPA and other documents, including EPA's 2003 IRIS Needs Assessment, the Office of Research and Development's multiyear plans, numerous documents outlining the IRIS assessment process and draft proposed changes to the assessment process, EPA budget justification documents, and OMB's Program Assessment Rating Tool assessment that covered the IRIS program. We interviewed officials from EPA's National Center for Environmental Assessment who manage the IRIS assessment program, including the Center Director, the Associate Director for Health, and the IRIS Program Director; officials from other EPA program offices, including the Office of Air and Radiation; and officials from federal science and health agencies that are involved in the IRIS assessment process, to obtain their perspectives on, among other things, the current IRIS assessment process, the potential effects of the draft proposed changes to the process, the extent to which EPA has made progress in completing assessments and meeting user needs, and challenges EPA faces in completing assessments. In addition, we interviewed officials from the Department of Defense, the Department of Energy, and the National Aeronautics and Space Administration who have served on the interagency working group on the IRIS assessment process, and OMB officials in the Office of General Counsel and the Office of Information and Regulatory Affairs to obtain their perspectives on the OMB/interagency review process and on the planned changes to the IRIS assessment process. We also interviewed officials from the Department of Health and Human Services' Agency for Toxic Substances and Disease Registry (ATSDR), an agency that assesses the potential noncancer health effects of exposure to some chemicals, to obtain information on ATSDR's assessment process. In addition, we attended the Board of Scientific Counselors Human Health Risk Assessment (HHRA) Subcommittee meetings in November 2007. During these meetings, the Subcommittee reviewed the EPA Office of Research and Development's HHRA program—specifically, its relevance, quality, performance, and scientific leadership.

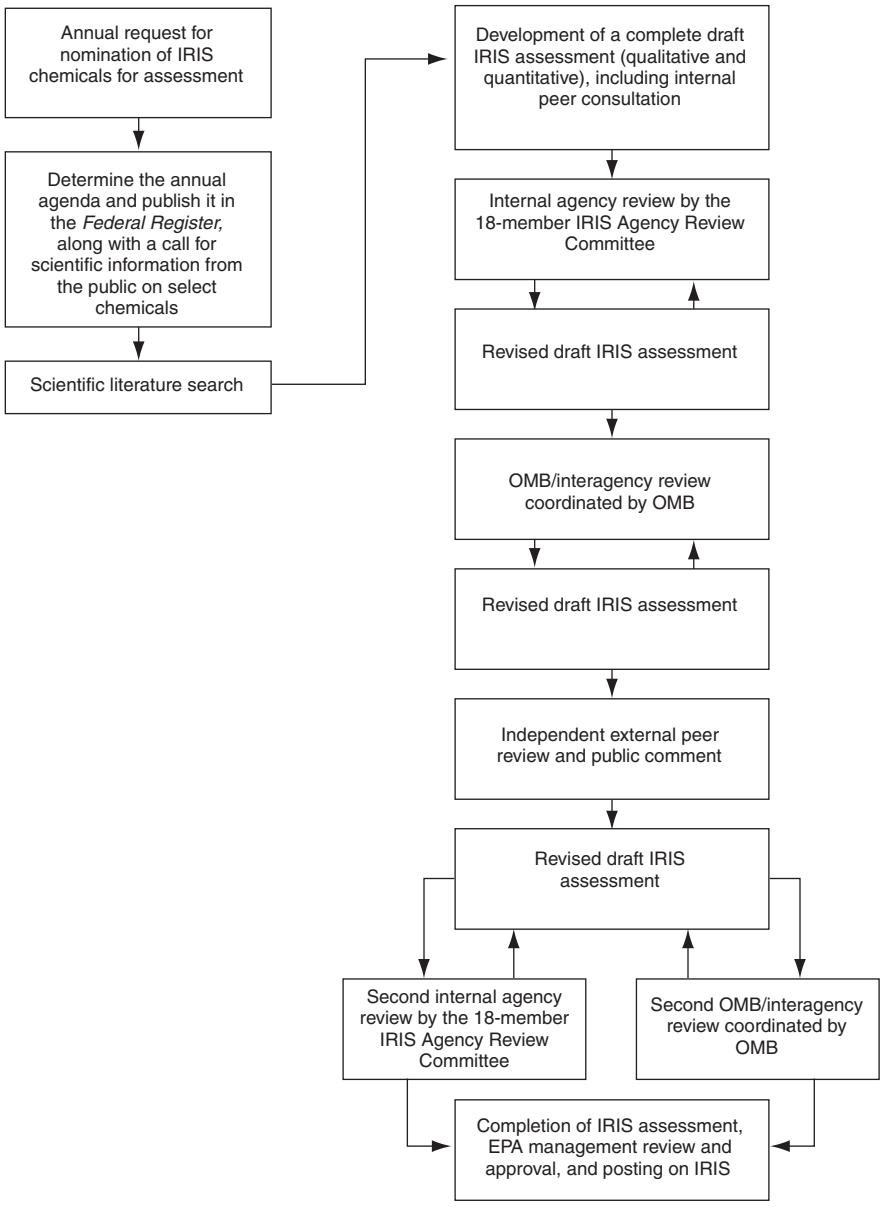
For the first objective, we obtained and analyzed several data sets, including data from EPA's IRIS database; EPA's IRIS Track—a compilation of status reports for IRIS assessments in progress; *Federal Register* notices announcing annual IRIS agendas; a spreadsheet that EPA uses to track the IRIS assessments sent to OMB for the OMB/interagency reviews; EPA's 2003 screening level reviews report—its efforts to identify assessments that may need to be updated; and EPA's 2003 IRIS Needs Assessment. From the data we gathered, we analyzed information on EPA's productivity, including the number of new and completed IRIS assessments, for fiscal years 2000 through 2007; the status of IRIS assessments, as of December 1, 2007, that were in progress during fiscal year 2007; the status of IRIS assessments that have been sent to OMB for OMB/interagency review and the time elapsed during those reviews; the number of assessments in the IRIS database that may need to be updated; the resources provided to the program for fiscal years 2000 through 2007; and user needs and EPA's assessment completion goals. We also interviewed chemical managers, who are responsible for managing the IRIS assessments in progress, to obtain further information on the 77 chemicals in progress during fiscal year 2007. We did not evaluate the scientific content or quality of IRIS assessments.

In addition, we conducted a reliability review of the data we received from EPA for our first objective. Through our review, we determined that the data we used were sufficiently reliable for our purposes. Our assessment consisted of interviews with officials about the data system and elements and the method of data input, among other areas. We also corroborated the data with other sources, where possible. For example, we verified the information provided in EPA's IRIS Track system with the chemical managers responsible for each of the 77 chemicals in progress during fiscal year 2007, and updated the information as appropriate. Similarly, we ensured that status information presented in IRIS Track was consistent with the status information presented in the spreadsheet that EPA uses to track draft assessments provided to OMB for the OMB/interagency review. In addition, EPA attempted to corroborate its data on the status of IRIS assessments that have been sent to OMB for OMB/interagency review and the time elapsed during those reviews, providing OMB with its tracking spreadsheet for review. OMB chose not to respond. Consequently, we relied on EPA's data and assessed its reliability, based on information including the source of the data and method of input.

We conducted this performance audit from October 2006 to March 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient,

appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Broad Outline of EPA's Current IRIS Assessment Process



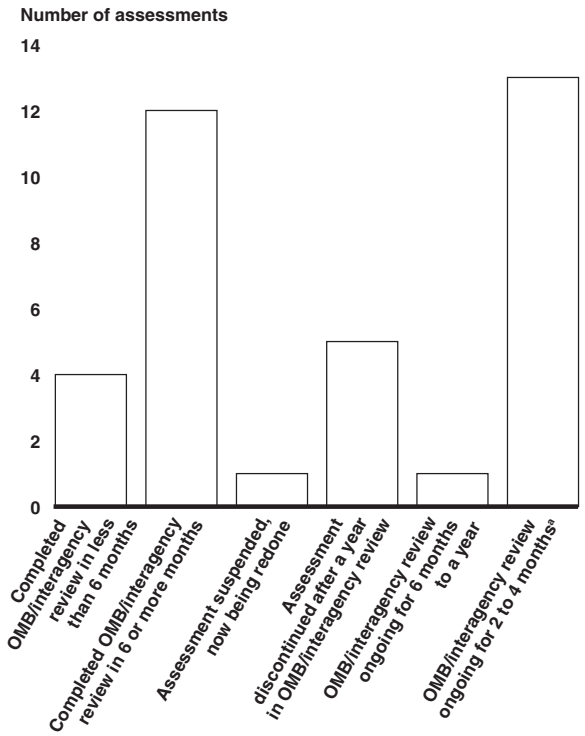
Source: GAO analysis of EPA information.

Note: This outline does not include the individual activities, including internal reviews and briefings, encompassed within many of the broad IRIS assessment categories.

Appendix III: Information on OMB/Interagency Reviews of IRIS Assessments

As of December 1, 2007, EPA has sent 36 draft IRIS assessments to OMB for the first OMB/interagency review managed by OMB, and the reviews of 16 assessments were completed. As shown in figure 6, the OMB/interagency review of 4 assessments was completed in less than 6 months and 12 of these assessments added 6 or more months to the IRIS assessment process.

Figure 6: Status of IRIS Assessments Sent to OMB for the First OMB/Interagency Review Starting in Fiscal Year 2004, as of December 1, 2007



Source: GAO analysis of EPA data.

[a]These 13 assessments were submitted to OMB in the last quarter of fiscal year 2007.

Moreover, as also shown in figure 6, five assessments that assessed acute exposure were discontinued at the direction of OMB after a year in the

OMB/interagency review stage,[1] and one assessment was suspended and is now being redone (naphthalene). Finally, 14 assessments were at the OMB/interagency review stage as of December 1, 2007: Of these, 1 had been at this stage for 9-½ months, and the remaining 13 had been submitted to OMB in the last quarter of fiscal year 2007 and had been at the OMB/interagency review stage for 2 to 4 months. While OMB officials said that EPA does not have to provide a document addressing every OMB/interagency comment, EPA officials said that a detailed disposition of comments document was, in fact, necessary in order to get OMB's agreement that EPA had satisfactorily addressed all comments. There are no time frames for this iterative process.

OMB officials said that the second OMB/interagency review is conducted by OMB to ensure that EPA has adequately considered the comments from the external peer review panel. As of December 1, 2007, 10 assessments had been sent to OMB for the second OMB/interagency review, and 5 of these assessments completed the review. The time frames for these five assessments ranged from 10 days to almost 4 months.

[1]These five assessments address short-term health risks. According to EPA, while OMB had previously agreed that these assessments would be included in EPA's 2006 annual performance goals that OMB uses to evaluate EPA's performance, in November 2007, OMB told EPA that it would not count EPA's short-term assessments toward meeting its goals, thereby lowering EPA's performance rating by OMB.

Appendix IV: Comments from the Environmental Protection Agency

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 21 2008

OFFICE OF
RESEARCH AND DEVELOPMENT

John B. Stephenson, Director
Natural Resources and Environment
Government Accountability Office
441 G Street NW, Room 2135
Washington, DC 20548

Dear Mr. Stephenson:

Thank you for the opportunity to review and comment on the Government Accountability Office's (GAO) draft report, "Low Productivity and Lack of Transparency Limit the Usefulness and Credibility of EPA's Integrated Risk Information System" (IRIS). Recognizing that EPA will, in all probability, respond to the final version, I would like to comment briefly on the productivity and transparency issues that are discussed in the draft report, which we believe are misrepresented in the report's title and throughout the report.

See comment 1.

See comment 2.

Since GAO raised many issues already recognized by EPA, the Agency has been actively working on revisions to its IRIS process. We believe these revisions will improve the productivity and transparency of IRIS. It should be noted that although GAO discusses some of the aspects of EPA's ongoing efforts to update the IRIS process, and comments on the potential effects of the proposed changes to the process, the GAO draft report refers to an outdated draft (internal) document. Consequently, some of the steps or procedures presented by GAO in its draft report have changed or will no longer be relevant in the final process. GAO's draft report should acknowledge that they were working from a draft internal document, and therefore that GAO's conclusions and recommendations may be erroneous when compared to the final IRIS process. Nonetheless, EPA will consider each of the GAO's recommendations in light of the new IRIS process, even though these recommendations were based on the outdated draft document.

See comment 3.

Under the new process, EPA's increased involvement of other agencies and the public will help us identify scientific issues earlier and foster better communication and sharing of information, which will ultimately help streamline the IRIS process. It is worth noting that under the new process, specific time limits for each step in the process will improve the timeliness of completed assessments. For example, public and

See comment 4.

See comment 5.

See comment 6.

See comment 7.

See comment 8.

See comment 9.

interagency review periods will be for fixed and relatively short durations. Interagency and public review will therefore represent only a small fraction of the total time required to complete an IRIS assessment. For most chemicals, the IRIS process will take between three and four and a half years. For the small number of mission-critical chemicals, the process may take an extra one to one and a half years. EPA believes the new IRIS process, in combination with the increased resources for the program provided in recent years, will lead to increased productivity in achieving completed assessments.

Although only briefly recognized in GAO's draft report, today's IRIS assessments are much more sophisticated, complex, and of higher scientific quality than at any other time in the program's history. The increased complexity of chemical assessments often leads to extensive public comments and more rigorous levels of internal and external peer review, which is one of the most important reasons for delays in the IRIS process. Additionally, recent external peer reviews by EPA's Science Advisory Board (SAB) and the National Academy of Sciences (NAS) have requested that even more sophisticated analyses, such as quantitative uncertainty analysis, be performed and presented in some IRIS assessments. These issues, and EPA's responsiveness to them, are given too little attention or are unfairly criticized in the GAO draft report.

Also, the IRIS program has increased the rigor of its scientific peer review. Specifically, the external peer review process has been changed from letter reviews to face-to-face panel peer reviews that are open to the public. This has encouraged public interaction with the peer reviewers. Members of our Board of Scientific Counselors (BOSC) that recently reviewed the IRIS program indicated that "the extent of peer review for IRIS . . . exceeds most other examples with which the subcommittee members were familiar."

Transparency is critical to an effective IRIS process. It is equally important that scientists and policymakers be able to have full and frank discussions. Clearly, the quality of government decisions is better and stronger when healthy skepticism is not discouraged. The current IRIS process strikes a balance between these two principles by encouraging open discussion of science and science policy questions, while appropriately protecting the deliberative process. Enhancing transparency through these and other measures necessarily means bringing many parties into the IRIS process. However, increased participation does not diminish EPA's accountability as the final decision-maker in establishing IRIS health values. All final IRIS assessments must also stand on their own merit by undergoing public and external peer review. It is noteworthy that in addition to having a transparent process, it is important to ensure transparency in the content of IRIS assessments (e.g., the rationale for relying on or using specific data sets, assumptions, or models). The GAO draft report does not comment on this facet of transparency, which directly bears on the content and quality of IRIS assessments.

See comment 10.

See comment 11.

See comment 12.

We have taken a number of specific steps to enhance transparency in the IRIS program. For example:

- We created *IRIS Track* on our web site to let everyone know the status of every chemical being worked on by EPA. This step opened up the process to all stakeholders, provided much greater transparency than before, and enabled interested parties to follow the progress of an assessment.

- Final documents are now published on the IRIS public web site. This includes all external public comments received and all the responses to the comments. The entire record of the assessment available to the public.

- IRIS has expanded the nomination process for new assessments to include a Federal Register Notice to allow the public to nominate chemicals, as well as a direct request to EPA Offices and other federal agencies asking for their nominations as well.

Like GAO, the Environmental Protection Agency highly values the IRIS Program, which stands as a model for: the international scientific community of unbiased, public, external peer review; the application of new scientific advancements in risk assessment; and focusing government efforts on priority chemical risk issues. According to the most recent review of the IRIS program by BOSC, "The comprehensiveness, transparency, and consistency of the IRIS approach has made it into the internationally-recognized standard in hazard characterization."

EPA is committed to continual enhancement of the IRIS Program, and in that spirit, we appreciate your attention to the program. If you have any comments or questions on our response, please contact me or Kevin Teichman, Deputy Assistant Administrator for Science, at (202) 564-6620.

Best regards,

George Gray
Assistant Administrator

The following are GAO's comments on the Environmental Protection Agency's letter dated February 21, 2008.

GAO Comments

1. Our analysis of the draft proposed changes to the IRIS assessment process does not support EPA's assertion that the revised process EPA is developing will improve the productivity and transparency of IRIS. In fact, as discussed in our draft and final reports, the draft proposed process would exacerbate existing productivity and transparency concerns.

2. EPA emphasizes that our draft report includes information on proposed revisions to the IRIS assessment process that "have changed or will no longer be relevant" in the final version. Our draft and final reports clearly indicate that we are providing information on EPA's current assessment process as well as on proposed changes to the IRIS process that EPA has been developing for years—but has not yet finalized. For example, the draft and final reports state that "as of December 2007, EPA was planning to send a revised draft back to the interagency work group for review and approval." Moreover, in the draft and final reports, the graphic outlining the proposed changes is titled "EPA's Draft Proposed IRIS Assessment Process." Further, we made our recommendations with the intent that they be considered and integrated into any revised process that EPA finalizes. Finally, we note that EPA did not identify any significant changes it has made to the proposed process we outline in the draft and final reports, either when it commented on the draft report or on a December 2007 statement of facts provided to EPA for review for factual accuracy. However, to ensure clarity, we have added "draft" prior to our use of the term "proposed process" in a number of places.

3. EPA states that "under the new process," the increased early involvement of other agencies and the public in identifying scientific issues and sharing information will ultimately help streamline the IRIS process. We note that other agencies and the public have the opportunity for early involvement in IRIS assessments under the current process. We do not believe that simply formalizing their involvement will, in fact, streamline the process or improve the timeliness of completed assessments.

4. We have revised the report to add the updated estimated time frames for IRIS assessments under EPA's proposed revisions to the process provided in EPA's letter. With most assessments estimated to take up to 4-1/2 years to complete, it appears unlikely that the IRIS program

will be able to produce quality assessments in a timely manner. As discussed in our draft and final reports, when assessments take longer than 2 years, they can become subject to substantial delays stemming from the need to redo key analyses to take into account changing science and assessment methodologies. Further, although EPA states that only a small number of IRIS assessments will be designated as mission-critical, we note that the chemicals with this designation are likely to be those posing widespread public health concerns that need to be addressed expeditiously. As we state in the draft and final reports, effectively maintaining the IRIS database will depend on strict adherence to time frames using the best available science.

In addition, we believe that if EPA grants special rights to other federal agencies to, among other things, suspend IRIS assessments to conduct new research, it is likely that the agency would face pressure to do so for other entities, including industries and individual companies that could be impacted by IRIS assessments should they lead to regulatory actions. Therefore, while EPA's stated intent is to limit the number of mission-critical designations made by other federal agencies, the number is likely to increase over time.

5. While EPA states that the draft report only briefly recognizes that IRIS assessments are more sophisticated and complex, our draft and final reports identify the growing complexity of risk assessments and risk assessment methods and models as one of five key factors contributing to EPA's inability to complete IRIS assessments in a timely manner.

6. EPA states that external peer reviews have requested that more sophisticated analyses, such as quantitative uncertainty analysis, be performed and presented in some IRIS assessments. EPA further states that its responsiveness to these requests is given too little attention or is unfairly criticized in the draft report. In fact, our draft and final reports clearly state that peer reviews of EPA's assessments have sometimes recommended additional uncertainty analysis. Further, while we conclude that it is appropriate for EPA to identify key uncertainties in IRIS assessments and to continue to work on developing methodologies for conducting more sophisticated and meaningful uncertainty analyses, the methodologies are not yet developed. That is, our draft and final reports indicate that EPA plans to release draft reports in 2010 on methods for analyzing and characterizing uncertainty in hazard and dose response and in physiologically based pharmacokinetic models. Thus, we believe that continuing to delay IRIS assessments to develop and test enhanced

methodologies and strategies for communicating them conflicts with EPA's stated goal of seeking balance among fairness, accuracy, and efficient action. Specifically, it is unclear how EPA's ongoing, nearly 2-year delay of the assessment of tetrachloroethylene (perc)—a widespread groundwater contaminant—pending the development of an acceptable uncertainty analysis represents an appropriate balance between accuracy and efficient action.

7. The draft and final reports discuss the changes EPA has made to its IRIS assessment process, including the one highlighted in EPA's letter—a change from letter peer reviews to panel peer reviews open to the public.

8. EPA states that the current IRIS process strikes a balance between transparency and having full and frank discussions by encouraging open discussion of science and science policy questions while appropriately protecting the deliberative process. We disagree that such a balance exists because the OMB/interagency review process is not transparent at all. In its comments, EPA dismisses any impact of the opaque OMB/interagency review process, emphasizing that all IRIS assessments undergo public and external peer review. However, the presence of transparency at a later stage of IRIS assessment development does not excuse or explain its absence earlier. Further, the National Academies have stated that the dialogue between risk assessors and risk managers should not bias or otherwise color the risk assessment conducted, and risk assessment and risk management activities should remain distinct. Transparency in the IRIS assessment process can provide assurance that these scientific assessments are appropriately based on the best available science and that they are not impacted by policy issues and considerations. Finally, because federal agencies' comments on IRIS assessments provided via the OMB/interagency process are to be scientific in nature, it is unclear why agencies would not candidly comment on an IRIS assessment even if their comments would become part of the public record.

9. EPA's comments note that transparency is applicable to both the assessment process and the content of IRIS assessments (e.g., the rationale for relying on or using specific data sets, assumptions, and models). We have revised our report to recognize that transparency is relevant to both the assessment process and the content of IRIS assessments and to be clear that the transparency issues we discuss primarily relate to the process. We note that many of the process changes EPA has made beginning in the 1990s are aimed at improving

the transparency of the content of IRIS assessments as well as the process.

10. This information on EPA process improvements is provided in the draft and final reports.

11. EPA stated that final IRIS documents are now published on the IRIS public Web site and that the entire record is available to the public. This statement is not accurate because the record of the OMB/interagency review comments and EPA's responses to them are not made available to the public.

12. The draft and final reports provide information on EPA's nomination process for new assessments, which includes a *Federal Register* notice.

Appendix V: Comments from the Office of Management and Budget

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

FEB 21 2008

Mr. John B. Stephenson
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, N.W., Room 2075
Washington, D.C. 20548

Dear Mr. Stephenson,

Thank you for the opportunity to comment on the Government Accountability Office's (GAO) draft report titled, "Chemical Assessments: Low Productivity and Lack of Transparency Limit the Usefulness and Credibility of EPA's Integrated Risk Information System" (GAO-08-440).

We applaud your efforts to evaluate the EPA Integrated Risk Information System (IRIS) as we believe this is a very important EPA program. As your report states, funding for the IRIS program has increased—from $1.7 million in FY 2000 to $9.6 million in FY 2007; OMB has supported changes that will improve the quality and efficiency of the IRIS program.

However, the draft GAO report fundamentally misunderstands the purpose of interagency review and, unfortunately, could leave readers with a false impression of the role of OMB/interagency review in the IRIS process. We discuss below our most important concerns with the draft report.[1]

See comment 1.

First, the draft report mischaracterizes OMB's role by alleging that OMB has imposed an OMB-managed interagency review process of IRIS risk assessment documents that has resulted in a loss of EPA control.[2] In fact, however, only EPA has the authority to finalize an EPA assessment and only EPA has authority to determine when a draft may be sent for external peer review. The interagency review process is a dialogue that helps to ensure the quality (including objectivity and transparency) of agency documents. Input from scientists throughout the Federal government (including, for example, HHS, DOD, DOE, NASA, DOL, and USDA within the context of the IRIS process) helps inform and improve the quality of IRIS assessments. These reviews address the objectivity, clarity, and transparency of the work, identifying key science policy issues for EPA's consideration, and scientific issues for external peer review.[3] Simply

See comment 2.

[1] In January 2008, GAO provided OMB staff with the opportunity to provide comments on the draft report titled "Statement of Facts for GAO's Review of EPA's Integrated Risk Information System." As you were aware, from our discussion on January 18, 2008, OMB staff had a number of concerns about the draft statement of facts, which were discussed in the January 22, 2008 comments that were sent to you. It appears that many of those comments have not been incorporated into the current draft report and our concerns remain. But rather than reiterating them all here, I will highlight our overarching comments on the draft report.

[2] Draft report, pp. 22-27.

[3] OMB has a broad interest in the quality, objectivity, utility and integrity of information disseminated by Federal Agencies. *See* OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002), *available at*

put, the interagency review process works as follows: OMB oversees an interagency process that is part of a broader EPA process. During the interagency process, EPA works collaboratively with OMB and other agencies to achieve resolution and completion of interagency reviews. These discussions have sometimes required resolution by the EPA Science Advisor, who is also the EPA Assistant Administrator of the Office of Research and Development. When this review process is complete, OMB concludes interagency review. At that time, EPA moves to the next step – generally, release of the risk assessment for public comment and an external peer review by a group of independent experts.[4] To be clear, EPA is entirely responsible for the content of information on IRIS.

See comment 3.

Second, the draft report alleges that the fact that OMB manages and directs the review process has "made it more difficult for EPA to complete IRIS assessments in a timely manner."[5] The draft report asserts that the OMB/interagency review adds significant time to IRIS time frames. It is our experience, however, that the interagency commenters have generally provided comments in a very timely manner. We are not aware of delays over "nonsubstantive issues" as alleged in the draft report.[6] We also note that the draft report does not provide specific examples on which we can comment.[7] In addition, we believe the draft report is seriously flawed in that it does not consider whether interagency review operates to improve the quality of IRIS assessments, both by addressing the objectivity, clarity, and transparency of the work as well as identifying key science policy issues for EPA consideration and technical issues for peer review.[8] The draft report's focus on timeliness, without consideration of quality of the end product, presents a misleading and incomplete picture.

See comment 4.

See comment 5.

Third, the draft report alleges that "the OMB/interagency review process also affects the credibility of assessments primarily because the review process lacks transparency."[9] To address this supposed issue, the draft report recommends that EPA make public comments by OMB and other Federal agencies to decision makers, the Congress, and the public. However, the draft report fails to acknowledge that, in the case of documents that involve interagency deliberations, these documents are covered by the deliberative process privilege, a well-recognized privilege that has been affirmed by the Congress in the Freedom of Information Act (5 U.S.C. 552(b)(5)) and by the Supreme Court in such cases as *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975),

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http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf; OMB's Final Information Quality Bulletin for Peer Review (2002), 70 Fed. Reg. 2664 (Jan. 14, 2005), *available at* http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf; and the OMB/OSTP Updated Principles for Risk Analysis, *available at* http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf.

[4] OMB recognizes that there is also a second round of interagency review in the current IRIS process. This review seeks to ensure that comments from expert reviewers and the public have been transparently and objectively addressed.

[5] Draft report, p. 22.

[6] Draft report, p. 25.

[7] In fact, when the draft report does provide a specific example, such as its discussion of naphthalene, it does so inaccurately. Draft report, pp. 36-38. OMB staff does not agree with the characterizations as presented in the draft report and suggests that readers would benefit from looking at the EPA documentation.: (i) the EPA charge for the peer consultation, which resulted from interagency dialogue, *available at* http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=46877; and (ii) the peer consultation report, *available at* http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=442588.

See comment 6.

[8] In fact, the draft report recognizes that it "did not evaluate the scientific content or quality of IRIS assessments." Draft report, p. 3.

[9] Draft report, p. 26.

and *EPA v. Mink*, 410 U.S. 73 (1973).[10] Accordingly, protection of internal Executive Branch communications is not "inconsistent with the principle of sound science," contrary to the erroneous conclusions of the draft report.[11] In fact, the National Academy of Sciences, which is recognized as a leader in scientific reviews, uses a multi-step review process that includes deliberations that are withheld from the public.[12]

See comment 7.

Finally, the draft report discusses at some length a draft document that it alleges serves to establish a "formal IRIS assessment process" that EPA has been developing over the past two years.[13] The discussion in the draft GAO report is misleading to readers; EPA's draft document is not a final document.[14] EPA has not completed the development of this process. Indeed, the process will not be complete until EPA circulates its draft to the public for comments and then releases a final product that is responsive to those comments.

Thank you again for the opportunity to review and comment on your draft report. We hope you take these comments into account in preparing your final report.

Sincerely,

Kevin F. Neyland
Deputy Administrator
Office of Information
and Regulatory Affairs

See comment 8.

[10] We do not consider the interagency process to constitute peer review; rather the document that EPA releases at a later step in the process will be subject to external peer review and public comment. EPA has a very transparent process by which draft IRIS assessments are released for public comment and external peer review before they are issued as final documents. The credibility of IRIS assessment is in part based on this rigorous and transparent external peer review and public comment process.

See comment 9.

[11] Draft report page 6.

[12] *See* http://www.iom.edu/CMS/6008.aspx and http://www.nationalacademies.org/studycommitteprocess.pdf. In 1997, Congress ensured that NAS deliberations have heightened confidentiality protections, when Congress passed stand-alone legislation that added a new section (Section 15) to the Federal Advisory Committee Act (5 U.S.C. App.) which specifically, and solely, addresses NAS and the National Academy of Public Administration. See the Federal Advisory Committee Act Amendments of 1997, Public Law 105-153, 111 Stat. 2689. The legislative history explains that Congress granted this protection "to preserve the quality of the research provided to the Federal Government through the National Academy of Sciences and the National Academy of Public Administration." Statement of Rep. Horn, Cong. Rec. H10579 (daily ed. November 9, 1997). Representative Horn explained that "[t]he administration, the House and the Senate, both the majority and minority, all agree the academy should not be subject to the full process of the Federal Advisory Committee Act." *Id.* As Rep. Horn also noted, *id.*, Congress passed this legislation in response to the court decision earlier that year in *Animal Legal Defense Fund, Inc. v. Shalala,* 104 F3d 1209 (D.C. Cir.), *cert. denied*, 522 U.S. 949 (1997), in which the court held that NAS panels were subject to the full range of FACA disclosure requirements. In its decision, the court stated that NAS, in arguing for why it should not be subject to these requirements, referred to "the deleterious effects of FACA's requirements on its deliberative processes: As the NAS sees it, open meetings and records would compromise its internal review procedures and inhibit candid exchange among its members." *Id.* at 428.

[13] Draft report, pp. 45-52.

See comment 10.

[14] By way of comparison, we note that, in providing to us the draft report for our comment, your cover page stated that the draft "is restricted to official use only"; is "subject to revision"; and "must be safeguarded to prevent improper disclosure."

The following are GAO's comments on the Office of Management and Budget's letter dated February 21, 2008.

GAO Comments

1. OMB states that the draft report mischaracterizes OMB's role by alleging that OMB has imposed an OMB-managed interagency review process of IRIS risk assessment documents that has resulted in a loss of EPA control. We believe that we have appropriately described the OMB/interagency review process and identified the time frame and assessment content limitations it has placed on EPA. First, as discussed in the draft and final reports, OMB has limited EPA's ability to determine the types of assessments it will conduct to meet its program needs by requiring EPA to terminate five IRIS assessments. Second, while EPA's annual performance goal for IRIS assessments had been the number of completed assessments, during the Program Assessment Rating Tool review by OMB it was agreed that the number of assessments provided to OMB for OMB/interagency review was the most appropriate annual measure of performance because EPA "relinquishes direct control of production dates" when it sends draft IRIS assessments to OMB. Third, our draft and final reports are clear that EPA officially determines when drafts are sent for external peer review or are finalized, but they are also clear that prior to taking these steps, EPA must be notified by OMB that EPA has adequately addressed interagency comments. Thus, the current process elevates the goal of reaching interagency agreement above achieving IRIS program objectives and in doing so fails to adequately acknowledge the expertise of EPA scientists and the many other scientific experts who have prepared and reviewed the assessments. Importantly, the fact that the first assessment drafts that become publicly available—those provided to independent peer reviewers—incorporate changes from federal agencies that may be affected by the assessments without identifying these changes or the reasons they were made weakens the credibility of the assessments. Finally, because the negotiations over OMB/interagency comments are not disclosed, OMB's assertion that EPA is entirely responsible for the content of information on IRIS is open to question.

2. GAO provides statements of facts to agencies to confirm the factual accuracy of statements upon which reports are based. OMB commented that we did not incorporate its concerns about the draft statement of facts we provided to OMB. We considered OMB's comments that addressed factual information and, in response, made some revisions as appropriate. However, many of OMB's comments did not address facts but were focused on broader issues, such as the

scope and methodology of our review. We disagreed with OMB's broad comments and thus did not make certain changes OMB suggested. For example, OMB expressed concern that our report discusses the development of proposed revisions to EPA's IRIS assessment process, which has not been released for public comment. As we discuss further in comment 10, GAO audits and reviews include those providing prospective analyses of possible or planned agency actions.

3. OMB takes issue with our conclusion that the OMB/interagency review has made it more difficult for EPA to complete IRIS assessments in a timely manner. Our draft and final reports show that the initial OMB/interagency reviews that had been completed as of December 1, 2007, added 6 months or more to the IRIS assessment process. The average length of time for these initial reviews was 7-1/2 months. Given the impact of delays on IRIS assessments and the staff time needed to respond to OMB/interagency comments, we believe such delays are significant. Further, our report discusses five key factors that make it difficult for EPA to complete assessments in a timely manner—one of which is the OMB/interagency review process.

4. OMB states its belief that the draft report is seriously flawed because it does not consider whether interagency reviews improve the quality of IRIS assessments. As OMB notes, our draft report states that we did not evaluate the scientific content or quality of IRIS assessments. However, as the draft and final reports state, the Board of Scientific Counselors—an independent board of experts appointed by EPA to assess its programs—reviewed the effectiveness of the IRIS program (as part of its review of EPA's human health risk assessment program) in November 2007. A report is expected to be finalized in early 2008. In response to our congressional request and to avoid duplication of effort, we focused on the timeliness and credibility of IRIS assessments in the context of the current assessment process and proposed revisions to it. Our draft report also noted that it is too early to determine whether or to what extent the IRIS assessment process changes EPA has implemented in recent years have enhanced the scientific credibility of the assessments—for example, only four assessments were finalized in fiscal years 2006 and 2007. Importantly, because OMB/interagency comments and EPA's response to them are not disclosed, the extent to which the comments added value or caused EPA to revise its risk estimates cannot be determined. However, the status of the IRIS assessment of dibutyl phthalate raises questions about the extent to which the OMB/interagency reviews improve the quality of IRIS assessments. Specifically, this key assessment had cleared both OMB/interagency reviews and was in the

process of being finalized in July 2007. However, because of methodology concerns raised by the Natural Resources Defense Council and the Chairman, Senate Committee on Environment and Public Works, EPA suspended the assessment pending a review by the National Academies.

5. OMB asserts that "the draft report fails to acknowledge that, in the case of documents that involve interagency deliberations, these documents are covered by the deliberative process privilege," and that "accordingly, protection of internal Executive Branch communications is not 'inconsistent with the principle of sound science.'" Contrary to OMB's assertion, the report specifically acknowledges that OMB considers the documents at issue to be protected from disclosure because of their deliberative nature. Moreover, OMB's assertions concerning the deliberative process privilege are misleading and illogical. That is, OMB's comments fail to note that the deliberative process privilege protects internal and interagency communications from judicially compelled disclosure, an issue irrelevant to our report.[1] The privilege in no way prevents agencies from voluntarily disclosing such information.[2] OMB is thus arguing that because the scientific comments at issue might generally be protected from discovery in civil litigation, refusal to disclose them voluntarily in this specific context is necessarily consistent with the principles of sound science. OMB provides no citation or other support for this conflation of judicial and scientific procedures.

   Moreover, OMB's comments that the deliberative process privilege was affirmed in the Freedom of Information Act (FOIA) fails to acknowledge that FOIA requires federal agencies to disclose factual material in documents covered by the deliberative process privilege if the factual material can be reasonably segregated from the deliberative

[1]*NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 149 ("it is reasonable to construe Exemption 5 to exempt those documents, and only those documents, normally privileged in the civil discovery context"); *EPA v. Mink*, 410 U.S. 73, 86 (1973) (The Freedom of Information Act (FOIA) contemplates that the public is entitled to all memoranda or letters that a private party could discover in litigation with the agency).

[2]See *Chrysler Corp. V. Brown*, 441 U.S. 281, 293 (holding that exemptions from FOIA's general requirement to disclose agency documents do not prohibit agencies from disclosing information covered by the exemptions). In fact, OMB has voluntarily released information it considered to be protected from disclosure under FOIA, presumably because it saw some benefit in doing so. *NRDC v. U.S. Department of Defense*, 442 F.Supp.2d 857, 863 (C.D. Cal. 2006). It is unclear from the case which FOIA exemptions OMB believed were applicable.

material.[3] OMB's comment appears to assume that because a document passes from one agency to another all of its contents may be withheld from disclosure, a legally unsupportable assertion that courts have uniformly rejected, particularly in the context of attempts to withhold scientific information.[4] Indeed, to the extent that interagency comments on IRIS assessments reflect political and policy concerns rather than discussions of scientific issues, they would be easier to withhold from disclosure in court but harder to justify as part of the IRIS scientific assessment process.

In addition, OMB's comments do not distinguish between risk assessment and risk management decisions, such as the formulation of regulations. As discussed in the draft and final reports, IRIS assessments are not themselves regulations, and OMB and other agencies will have opportunities to engage in deliberative policy debates during, for example, interagency reviews that occur during rule makings. These are points in the process where it is appropriate to address policy questions, such as the implications for other agencies of a specific regulatory decision.

Finally, under the interagency process as currently contemplated, some IRIS assessment reviewers—representatives of federal agencies—essentially are given favored status. OMB fails to explain why certain scientific views should be given added consideration and protected from the critical scientific scrutiny all other comments will receive simply because the reviewers providing the comments are federal employees.

6. OMB stated general disagreement with information presented in our discussion of the naphthalene assessment but did not cite the specific

[3]E.g., *Mead Data Central, Inc. v. U.S. Dept. of Air Force*, 566 F.2d 242, 260 (D.C. Cir. 1977) ("The focus of the FOIA is information, not documents, and an agency cannot justify withholding an entire document simply by showing that it contains some exempt material.").

[4]E.g., *Bristol-Myers v. FTC*, 424 F.2d 935, 939 (FOIA "does not authorize an agency to throw a protective blanket over all information by casting it in the form of an internal memorandum. Purely factual reports and scientific studies cannot be cloaked in secrecy by an exemption designed to protect only those internal working papers in which opinions are expressed and policies formulated and recommended"); *Southwest Center v. Biological Diversity v. USDA*, 170 F.Supp.2d 931, 943 (D. Ariz. 2000) ("FOIA exemption five does not protect research data"); *Verrazzano Trading Corp. v. United States*, 349 F.Supp. 1401, 1406 (Cust. Ct. 1972) ("the exemption was not intended to protect factual or scientific reports and investigations").

information with which it disagreed. Instead, OMB referred readers to the charge and report from the second peer review EPA had conducted on this chemical at OMB's direction. In our draft and final reports, we report EPA officials' description of the purpose and conclusions of this peer review. Specifically, EPA officials said (1) the agency convened an additional expert review panel on genotoxicity to obtain recommendations about short-term tests that OMB thought could be done quickly and (2) the panel concluded that such research could not be conducted in the short term. The questions posed to the peer reviewers and the summary of results in the report cited by OMB are consistent with EPA's description.

7. OMB says that the draft report is misleading to readers because EPA's "draft document is not a final document." The report clearly identifies the proposed IRIS assessment changes that EPA has been working on. For example, the graphic outlining the proposed changes is titled "EPA's Draft Proposed IRIS Assessment Process." The draft and final reports also state that "as of December 2007, EPA was planning to send a revised draft back to the interagency work group for review and approval." However, to ensure clarity, we have added "draft" prior to our use of the term "proposed process" in a number of places.

8. We did not assert that the OMB/interagency process is equivalent to peer review, and we agree with OMB that this review process happens before any external peer review occurs. However, because the OMB/interagency process is opaque, neither peer reviewers nor the public are privy to the changes EPA made to the draft assessments or the charge questions to the peer review panels in response to the comments from OMB and other federal agencies. The presence of transparency at a later stage of IRIS assessment development does not excuse or explain its absence earlier.

9. It is unclear why OMB attempts to rely on the Federal Advisory Committee Act Amendments of 1997 to defend the lack of transparency in the interagency IRIS review process. The transparency procedures applicable to the National Academies' committees to which OMB refers far exceed those that exist under the OMB/interagency IRIS process. For example, under the legislation OMB cites, National Academies' committees must (1) provide the names, biographies, and conflict of interest disclosures of committee appointees; (2) provide an opportunity for the public to comment on the proposed committee member appointments; (3) ensure that meetings focused on data gathering are generally open to the public; (4) provide the names of reviewers of draft committee reports; and (5)

provide summaries of any closed committee meetings. 5 U.S.C. App. 2, § 15. The interagency portion of the IRIS process does none of these things. Moreover, while the act authorizes a National Academies' committee to close meetings at which information exempt from disclosure under FOIA would be discussed, the President of the National Academy of Sciences assured the bill's sponsor, in a letter commenting on the House bill that would later be enacted into law, that the Academy would not rely on the deliberative process exemption as the basis for closing a meeting.

"I wish to assure you that we subscribe fully to the goal of providing as much openness as possible in our work. In particular, we have no intention of using Section 552(b)(5), which deals with interagency memoranda, as a basis for closing meetings of Academy committees. In fact, it is the Academy's standard practice not to treat the type of material covered by Section 552(b)(5) as confidential input to any Academy deliberative process. This procedure insures that, inasmuch as possible, all the information that a committee uses to reach its conclusion is in the public record."

10. We were asked by the Chairman, Senate Committee on Environment and Public Works, to examine the potential effects of planned changes to the IRIS assessment process on EPA's ability to ensure that IRIS provides current, credible risk information. This review therefore involved evaluating a draft of EPA's planned IRIS assessment changes. GAO audits and reviews include those providing prospective analyses of possible or planned agency actions. We may also assess the ability of alternative approaches to yield better program performance or eliminate factors that inhibit program effectiveness. As is typical in cases in which we evaluate draft proposals, we make our recommendations on the IRIS assessment process in the spirit of informing those revisions.

Appendix VI: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, Christine Fishkin (Assistant Director), Mark Braza, Nancy Crothers, Laura Gatz, Richard P. Johnson, Summer Lingard, Susan Swearingen, and Delia Zee made key contributions to this report. Also contributing to this report were Tim Bober, Phylis Cline, Michael Derr, and Cynthia Taylor.

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